UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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PLENARY SESSION

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February 5, 2008
8:15 a.m.

Key Bridge Marriott
Arlington, Virginia

CHAIR: MR. ALFRED V. ALMANZA
Administrator, FSIS

MODERATOR: MR. ROBERT TYNAN
Deputy Assistant Administrator
Office of Public Affairs
Education and Outreach

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MR. MIKE E. KOWALCYK

Free State Reporting, Inc.
1378 Cape St. Claire Road
Annapolis, MD 21409
(410) 974-0947

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I-N-D-E-X

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P-R-O-C-E-E-D-I-N-G-S

(8:15 a.m.)

MR. TYNAN: Good morning. Welcome to our National Advisory Committee on Meat and Poultry Inspection. This is our -- I guess our winter meeting. We usually do it fall and spring, but we're doing a winter meeting and have some very important topics that we need to talk with you about.

MS. TUCKER-FOREMAN: Hello. Hello.

MR. TYNAN: Okay. We have somebody on the line, and I will explain that in just a moment.

It's Super Tuesday. For those of you who are New York Giants fans, it's a very Super Tuesday. For those of us who are New England fans, if I break down and cry or anything like that, you'll understand completely.

We do have a super meeting for you and a very packed agenda over the next two days. Now you'll notice on your Agenda, we have a closing time of around 5:00 for the public comment period, and then we'll be adjourning probably shortly thereafter. So I am going to get into the business of the day. I

will be back in a few minutes to talk a little bit about the rules of the meeting and how we're going to proceed over Tuesday and Wednesday for our Advisory Committee meeting.

But with no further adieu, I'm going to introduce Dr. Richard Raymond, our Under Secretary for Food Safety, so that he can provide some opening remarks.

DR. RAYMOND: Thank you, Robert, and welcome everyone to as Robert said, the winter meeting. Robert, unless you're from Nebraska and bleed Husker Red, you don't know what pain and suffering is when a football team loses.

(Laughter.)

DR. RAYMOND: At least you're 18 and 1 instead of 0 and 9 or something like that.

(Laughter.)

DR. RAYMOND: It's nice to see the room fill up. I think maybe we've achieved one goal that we had set two and a half years ago, and that was to outgrow the South Building's cafeteria for these NACMPI meetings.

I was told a long time ago, when we started talking about risk-based inspection in processing plants, I was asked who are you going to use to vet that through besides just the Agency, and I said I plan on using the NACMPI Committee, so we'll have representatives from all walks of life telling us what we're doing right and what we're doing wrong. I was told that NACMPI are non-events. The Agency tosses them underhanded lobs so that you can hit home runs and look good, and they don't have anything on substance.

So that was two and a half years ago, and look at the crowd today because we do have things of substance to continue to talk about. These aren't new subjects, but they're new variations of old subjects.

I think we've come a long way since that meeting back in November 2005 when we did announce that we were going to begin to use NACMPI as a sounding board for risk-based inspection in processing plants and eventually risk-based inspection in slaughter, and we've kept our word to

that. We've had a series of public meetings as most of you know, most of you attended a lot of the public meetings, where again people from all walks of life have come and told us what they thought about the plans, good and bad, and they're good healthy debates I believe. We've taken a lot of what we've heard into consideration, and I believe we continue to build a system that will serve the American public and the people that we export to, the countries we export to, in a better fashion with a safer food supply because we all do have that same goal, and that's to improve the safety of our food supply, particularly meat, poultry and egg products that this Advisory Committee has a say in.

I do think somewhere along the line, we need to throw open the discussion, a broader discussion, a national discussion about food safety and what our highest risk products are, and I'm not talking just meat and poultry here. I'm talking about all food products, as we've seen the number of foodborne illnesses increase in produce, fruits, vegetables, et cetera. I think we need to have a

healthy discussion about what are the risky products and what level of inspection do those products get. We already have by statute a lot of determinations about what level of inspection meat and poultry products get, but I'd also like to throw open the discussion what are the lowest risk products and what level of inspection should the lowest risk products get, and that's part of our risk-based inspection system.

When ground poultry plants get the same amount of inspection as canned chicken soup plants, I think there's a problem. When a plant that's grinding beef gets the same amount of inspection as a plant that's putting cooked hamburger on pizza kits, I think there's a problem. But I think it relates into fresh tomatoes and ketchup, I think it relates into cantaloupe that's uncut and cantaloupe that's sliced and in bags. I think it relates to fresh raw spinach and cooked spinach. They all get the same level of inspection or, in some cases, lack of inspection, and I think that's a debate we need to expand, too, eventually but not today and tomorrow.

Today and tomorrow you're going to hear where the Agency is now at in its thought processes about risk-based inspection in processing and risk-based inspection in slaughter, and there's going to be some new stuff. You've done your homework. I assume you've seen, you've seen it in writing, that 700-page stuff on the web, most of which is appendices. So I hope you didn't read all the appendices but we felt if we didn't put the appendices there, of course, we would be criticized with a 30-page summary that says Appendix 1, Appendix 2. So it's there for as much time as you want to spend.

Now I want to point out very clearly today, this is definitely a work in progress. This is not a fait accompli. This is not the plan that we're going to roll out. In fact, I'll be honest with you, I disagree with some of the things that are on the web, and we've had discussions within the Agency trying to reach some compromises there, and we want to hear you as we build this.

This is a new shot at something that will

be far improved and better than what we intended to roll out in July last summer in those prototype locations. This is a product that will reflect where we're going in the Agency with the Public Health Information System which you will hear about, which will allow us to assure that there is more consistency within inspection from plant to plant, inspector to inspector, so we can use noncompliance reports with a higher level of confidence.

You will hear about the food safety assessments that will be done in the majority of the plants before we roll out the new risk-based inspection system.

You will hear about the OIG Report and the 35 recommendations that they made, and that we reach full management agreement with the OIG. We do believe that we meeting those 35 recommendations will give us a basis upon which to found this risk-based inspection in processing and slaughter. It is critical.

Now the timeline has changed because of these things that we must do. Like the Public Health

Information System and the food safety assessments in the majority of the plants. Those things take time, and until those things are done, we will not be rolling this out. So you have plenty of time, and everybody else in the room and everybody else that may read what goes on today that will come to our public meetings have plenty of time to continue to have their voices heard as we do build this.

There's some controversial things we're going to talk about today and tomorrow, that again, we will not agree on but I think we will agree on the end result, to build a better, safer food supply for meat, poultry and egg products. Let's just remember as we go down this path to try to work together to build that product. We have listened in the past. We will continue to listen, continue to modify, and the one thing that Joe Harris and I are probably going to lament to our death beds is the Nona Matrix Compromise --

MS. TUCKER-FOREMAN: This is Carol. I've called back in, and it says I'm connected, but I don't hear anything.

DR. RAYMOND: We hear you, Carol. Do you hear me? Carol?

Well, anyhow, Joe, the Nona Matrix Compromise that you worked so hard to get to the compromise and it was going to make a great novel story, the byline, the title, it's dead. It's gone. But what -- and I do thank you and everyone else for working through the Nona Matrix Compromise, but what you're going to hear about today and tomorrow, what you're going to see, is something that's going to be so much easier to explain than the Nona Matrix.

Joe, your members won't have to go home when they get a positive *E. coli* and do the math and try to figure out how much those 3 points count within the 35-point system, whether they move from Level 1 to Level 2 to Level 3. When they pop a positive, they're going to know they went to Level 3 if we go with what the Agency is proposing. They go to Level 3 for food safety assessment and then depending on what the food safety assessment shows, they may go back down to Level 2 or Level 1, but they'll know that night what's going to transpire

because of the positive. Other things are important. You'll hear about this. There's more ways you can get to Level 2 or Level 3.

Are you with us now, Carol?

MS. TUCKER-FOREMAN: Yeah, but I don't want it on this phone. I want to be connected through the line I called in on because I can just barely hear it.

DR. RAYMOND: All I can tell you is -- this is Dr. Raymond, Carol. You know I'm not a technician. I can't handle a computer, can't handle the phones. We've got someone working on it. So we'll get to it.

MS. TUCKER-FOREMAN: There's nothing happening on this line.

DR. RAYMOND: Robert, why don't we go on while they try to work with Carol. So is Al up next? Is that the -- I'll shut up so we can move on. We've been interrupted enough here. I just want to say it's been a good two and a half years. It's going to be a couple of years before this rolls out. I've got a little less than a year. So one of my dreams was

to get this done in my time. That dream won't happen, but the dream still lives. I want to get this far enough along during my last year that we can get as many hurdles out of the way as we can. I still have a passion for it as most of you do. So let's work together for the next 11 months at least, while I can still work with you, and let's get this moving as far down the road as we can.

Al.

MR. ALMANZA: Well, good morning, everyone. I want to thank everyone for coming to this meeting of the National Advisory Committee on Meat and Poultry Inspection, and we're going to have an ambitious agenda as you can imagine. Looking at those notebooks, you can tell it's not going to be short.

Over the next two days, we're going to be asking for your input on Public Health Risk-Based Inspection System. The goal of the system, which is science based and data driven, is to focus on our resources where they can best insure food safety systems are under control.

That focus, we believe, will help us achieve FSIS' public health mission. Your input is critical for us to best achieve that mission. I think you will agree that in order to be successful, public health decisions must be based on data. The Agency has made a good deal of progress in our collection, analysis and response to data including using data to predict problems before they occur. All of this effort is directed to better protect public health.

At our meeting last August, we jointly established the Data Subcommittee within NACMPI. That Subcommittee has been an instrumental part of this process and provided a tremendous amount of input on the topics that we discussed in this meeting.

I'd like to this --

MS. TUCKER-FOREMAN: Somebody come on and told me to stand by, but nothing has happened since then.

MR. ALMANZA: We're still working on it, Carol, if you can hear me.

I'd like to take this opportunity to publicly thank the members of the Subcommittee for the assistance that they have provided up until now. When we set up the Data Subcommittee, we committed to sharing our data and technical reports within NACMPI, and that's what we're doing here today.

I'm sure that you are all aware that before moving forward, to a more robust risk-based inspection system in processing, Congress and the Office of the Inspector General, OIG, told us that we needed to spend even more time examining our approach and making sure we have a strong data system and infrastructure in place.

By doing so --

MS. TUCKER-FOREMAN: I heard about three words from the speaker, and I'm not hearing anything else.

MR. ALMANZA: By doing so, the Agency can do a better job collecting, analyzing and using data in making public health decisions. I am confident that in the months to come, we'll be even better at what we do because we reexamined our system and

dedicated ourselves to strengthening our infrastructure.

FSIS has worked closely with OIG on this audit, and we're pleased that OIG agrees with our responses to 35 of its recommendations.

This morning, you will hear more about this, which I think will provide a good perspective for discussion that will follow. We will tie together the core issues of the report and how they have been integrated into the concept that we are outlining today and tomorrow.

One significant initiative is the development of the Public Health Information System that provides the foundation upon which the inspection system being considered would be built. PHIS will make data collection, analysis and reporting easier and quicker at all levels in the Agency. We'll provide an overview of PHIS this morning.

Following that, our discussion at this meeting will cover two major topics, the Public Health Risk-Based Inspection System in processing and

slaughter activities, and how the system would specifically apply in poultry slaughter. We'll discuss the concept of processing today and poultry slaughter tomorrow.

As Dr. Raymond noted, FSIS has actively sought input from our consumer, industry, scientific and academic stakeholders, from our public health and food safety partners, and also from our own employees.

We've made it a point to invite representatives from our employee organizations to come to these meetings and provide their valuable perspective.

At this time, I'd like to recognize representatives from our employee groups and thank them for being here. Mr. Stanley Painter from the National Joint Council of Food Inspection Locals, Dr. Chris Bratcher from the National Association of Federal Veterinarians, Mr. Robert McKee, Association of Technical and Supervisory Professionals, and Dr. Pat Basu, Asian-Pacific-American Network in Agriculture. Thank you all for being here.

So we have a lot to cover in the next two days. I want to thank you for taking time from your busy schedules to join us, and I look forward to hearing from each and every one of you, as we continue to strengthen our systems and make further strides in our mission to protect public health.

I'm going to turn it back over to Robert who will get us through the rules.

MR. TYNAN: Good morning again. I wanted to spend just a moment going through the rules of the meeting. We do this every Advisory Committee meeting, and I would refer the folks at the table to Tab 3, I believe it is, in your notebook that has the rules of the meeting.

I did want to point out that we do have a couple of our Committee members that will be participating by phone. As you know, you could hear Carol Tucker-Foreman's voice. We also have Dr. Catherine Cutter from Penn State that will be joining at different times during the meeting. The reason for that is both individuals participated on our Advisory Subcommittee. They have a lot of input

in terms of the materials that you're going to be looking at today, and so I felt it appropriate to depart from what we normally do with our Advisory Committee and allow for a phone hookup for both of them so that they can participate and give their perspectives on the task at hand.

Having said that though, we do evidently have a little bit of a technical difficulty, and we are going to try and correct that but we will continue to move on with the meeting as quickly as we can and try and get Mrs. Foreman and Dr. Cutter involved in the meeting whenever we can get those technical difficulties fixed.

But again, the meeting rules of order, essentially the Chair of the Advisory Committee is Mr. Almanza, our Administrator. He opens the meeting, recognizes those wanting to speak. We'll impose time limits if we are getting close to our time and will be the person that allows for the public meeting portion toward the end of the day, and certainly adjourns the meeting. Characteristically, Mr. Almanza, and I'm assuming he's going to do that

again today, will delegate that to me so that he can concentrate on the discussion and I can perform meeting management tasks. So hopefully that will work out very well.

All the questions or requests to speak normally are addressed to the chair. People must be recognized by the Chair before speaking. What we normally do every, every meeting is if you have a question on a particular issue, raise the tent card, stand it up on its end and then we'll find some way to move around the room in an orderly fashion and make sure everybody has an opportunity to comment.

Similarly with Dr. Cutter and Mrs. Foreman, obviously they can't raise a tent card for us but we'll take a moment to stop and see if they have any questions or issues on any of the topics that we're doing today.

The presentations will be followed by short question and answer periods. You'll see on the agenda, that in some cases, we've allowed 5 or 10 minutes for comments and questions. This is solely for the purpose of clarifying issues that come up

during that presentation. Obviously the folks that are prepared are trying to be as clear and concise as they possibly can. Obviously sometimes that doesn't necessarily resonate with you as the members of the Committee. So we allow a few minutes for you to ask a clarifying question.

We will, however, permit later on in the meeting a more robust discussion of all of the Committee on all of the topics. So, if we could during those five-minute periods, if we could confine it to addressing the issues that are at hand.

Speeches or statements of opinion by either the Committee or members of the audience, we would like you to register at the table outside, and we will permit those more lengthy comments to occur during the public meeting portion, which on the agenda is around probably between 4:30 and 5:30.

The Chair approves in advance any materials that are to be distributed for the meeting. So, if you have handouts from your organization, the public members, if you have materials that you want to hand out, please check with me at the break, before you

put them on the table out there for distribution.

I think number 6, the Committee members are expected to attend the plenary sessions that we'll have this morning. We also have Subcommittee meetings during the course of the day, and you'll see on the agenda, on both days, we're going to have Subcommittee sessions and report outs. So this is sort of a packed agenda for this meeting. So we need everybody to help in terms of responding to some of the issues.

But if you're assigned to a particular Subcommittee, our expectation is that you will participate in that Subcommittee. So, if you choose to go to another one or want to participate in another Subcommittee, please let us know during the break, and we'll try and make an adjustment so that everyone can utilize their expertise the way they want. We've set the committees up, sort of based on what we know about each individual, where your expertise would lie. For the Subcommittee people, we try to break those up on each of the committee deliberations for today. So we've tried to balance

the groups, but in doing that, we often miss a particular interest that some of the Committee members have. So we'll make an adjustment at the break.

The Subcommittee Chair is designated as the Chair and controls the Subcommittee deliberations, and this is very important. Members of the public may participate in those meetings. As I have said in the past, it is up to the Chairperson of that Subcommittee during the breakout to determine the amount of conversation that the public has during that meeting. So I allow the Chairpersons a lot of latitude in determining how those discussions will go. We also have provided for phone hookups for Dr. Cutter and Mrs. Foreman to participate on those as well.

And last but not least, these rules of order are subject to discussion at anytime, so that we can make any changes that are necessary to make sure that the meetings run efficiently.

Any questions from the Committee at this particular point?

(No response.)

MR. TYNAN: Okay. And again what we would like to do when we get to the -- after the presentations, if you have comments or questions, please stand the tent card up, we'll try and recognize you, if you could identify yourself and your affiliation, we do have a gentleman here that is recording the meeting as a public meeting. So we will have a transcript of the meeting. So it will be helpful to him, I think, to know who's speaking and what the affiliation is.

I'm not going to go through the agenda for today but I did want to mention that we have sort of two phases to the meeting. Today we're going to be talking about public health risk-based inspection in processing and slaughter activities, and then tomorrow we'll be speaking specifically about public health risk-based inspection specifically in poultry slaughter. So each day sort of stands by itself. They are parallel tracks. You'll see in the agenda that some of the topics are very similar, but we will be going until 5:00, 5:30 each day, and I think I

mentioned that after each, we'll have a short comment and question period. And I'm going to ask each of the presenters, because we do have such a packed agenda, to stay within the timelines that they have available for them. So, if we've allowed for 15 minutes and 5 minutes of questions, I'm hoping the presenters will honor that and stay within the 15 minutes we've allowed.

And with that, are there any questions on the rules or how we're going to proceed with the meeting?

(No response.)

MR. TYNAN: Then what I'd like to do at this particular point in time is go around the room so that everybody is introduced, and that will hopefully help our Reporter.

I'm Robert Tynan. I'm the Deputy Assistant Administrator in the Office of Public Affairs, Education and Outreach.

MR. SMITH: Bill Smith, Assistant Administrator, Office of Program Evaluation, Enforcement and Review.

DR. MACZKA: I'm Carol Maczka, Office of Food Defense and Emergency Response.

MR. GIOGLIO: Charles Gioglio, Director of Labeling and Program Delivery Division, Office of Policy and Program Development.

MR. ALMANZA: I'm Al Almanza, Administrator of FSIS.

DR. RAYMOND: Richard Raymond, Under Secretary for the Office of Food Safety.

MR. PAINTER: Stan Painter, Chairman of the National Joint Council of Food Inspection Locals.

DR. BRATCHER: Chris Bratcher, Past-President, International Association of Federal Veterinarians.

MR. McKEE: Bob McKee, ATSP representative.

MR. SCHAD: Mark Schad, Schad Meats, Cincinnati, Ohio.

MR. ELFERING: Kevin Elfering from New Mexico.

DR. HENRY: Craig Henry. I'm with Grocery Manufacturers Association.

MR. DICKSON: Jim Dickson from Iowa State

University.

MR. COVINGTON: Brian Covington, Keystone Foods.

MS. JONES: Cheryl Jones, Morehouse School of Medicine.

DR. STROMBERG: Stan Stromberg from the Oklahoma Department of Agriculture.

DR. HARRIS: Joe Harris with Southwest Meat Association.

DR. RYBOLT: Michael Rybolt, National Turkey Federation.

MR. KOWALCYK: Michael Kowalcyk with the Center for Foodborne Illness, Research and Prevention.

DR. NEGRON-BRAVO: Edna Negron from the University of Puerto Rico, Mayaguez Campus.

DR. GRONDAHL: Andrea Grondahl, North Dakota Department of Agriculture.

MR. TYNAN: Thank you very much. I appreciate it. And so we'll begin the meeting.

The first presenter that we have today is Mr. William Smith, and I'm going to ask him to come

up and do his presentation on the -- I beg your pardon. We've made a change. We're going to do this a little bit less formally. We're going to allow the presenters to stay at their table. We have a clicker so that they can move through their slide presentations.

Before we begin, is Mrs. Foreman able to join?

MS. TUCKER-FOREMAN: Can you hear me?

MR. TYNAN: Yes, we can, Carol. Can you hear us?

MS. TUCKER-FOREMAN: I'm okay now. It took a while but --

MR. TYNAN: Well, sorry for the technical difficulties. You're breaking up just a little bit. So when we get to the comment periods, we may ask you to maybe speak a little bit louder or do something with your phone so that we can hear you. I just introduced Mr. Smith, and he's going to do the presentation on the OIG Report. Bill.

MR. SMITH: Thank you, Robert. What I do want to talk to you about is the OIG Report that was

issued in December 2007, specifically issues impacting the development of the risk-based inspection in meat and poultry processing establishments.

As Dr. Raymond and Al Almanza said, there was 35 recommendations included in that Report, and I'd like to go over those.

We categorized them into four major principles using the language in the OIG Report.

So this is right out of the OIG Report. I think it is very germane to our discussion. A solid foundation for a risk-based program that focuses FSIS' inspection resources to protect public health should be based upon a system that uses four driving principles. Those principles are science and statistical analysis, based upon high quality, relevant data which focuses on risk analysis and prevention, effective integration of FSIS data management systems, strong information technology and infrastructure and lastly, effective management controls over inspection activities. And so I'd like to address each one of those.

Under principle one, our science and statistically relevant data, there was two major categories in those recommendations. First was that we identify how food safety assessments will influence the assignment of resources as they play a significant role in providing the most comprehensive assessment of an establishment's food safety system. And we're in total agreement with that finding.

Secondly, clearly define the scientific basis of how components of the in-plant inspection results, laboratory sampling, enforcement actions, in commerce information, will be utilized as an accurate characterization of an establishment's food safety control. And instead of going in depth in that right now, I think over the next two days' presentations, you'll see how we're going to meet those two main goals of this principle.

The next principle was effective integration of FSIS data management systems, and again, in this, there was three clarifying points. One was clearly articulate how the accuracy of inspection and production data will be substantiated,

clearly define the comprehensive use of data by the Agency to focus inspection resources on those areas of greatest risk to the public health. And lastly, complete a comprehensive Agency-wide examination of analytical and information needs including how or who would perform analysis, who needs the analysis and who takes action based on the analysis.

Again, over the next two days, we're going to be talking about how we will use, effectively integrate our data management systems. A couple of key points here, we're looking at how we're going to use data not only at the Headquarters' level but at the field level and also how the Headquarters and field levels will interact using this data.

I think it's also important that the systems that have this amount of data, what we've learned from conducting inspection over the last couple of years, as well as from the OIG Report, is that data mining need is an important function that that needs to be automated and the results of data analysis need to be programmed and then given to managers to react to.

In the past, we've had managers or supervisors and our inspection personnel in the plant, they're having to go through data in order to pick up trends and identify areas of concern and then react to those. But as you know, every inspection, every plant operates at a minimum of 240 days a year. Any inspector that has 3 or 4 plants, you just multiply that times 240. You have supervisors that have 20 employees and 50 to 60 plants, and as it goes up through the system, to 5400 plants that we regulate nationally, you can see there's quite a bit of data and to expect individuals to sort through that and then determine trends and relate laboratory results with inspection findings, with food safety assessments, can be a very daunting task, and a lot of that can be automated.

And you're going to see here that that is the plan of the data integration in the new system, so that again the results of data analysis, it can do this trend analysis or provide it to inspectors and supervisors and managers so they can react to problems instead of having to dig through data to

find them. And I think that's a big advantage that we're seeing here.

Principle 3 was strong information technology and infrastructure. And so the critical components of these recommendations focus on assure you have valid data, that you institute proper oversight and control during development and testing of critical IT applications that support the public health system, and then ensure you have capacity and security of your IT infrastructure to meet the requirements of implementing the public health system, and we take this very seriously also.

The system that you're going to be hearing about today will be built using the American National Standards Institute, Earn Value Management Standards procedures. Our software development is going to be under Life Cycle Development and that's a well-known standard to be applied. And as each component that you'll be hearing about today is developed, there will be performance testing to make sure that it functions as designed, and then user testing to see that the end user is going to be able to use the

system as the policy dictates that it should be.

So those are very important aspects, each step of the way, to assure that we have valid data and to assure that we have oversight and control during development.

We also know that security is extremely important, and the Agency is right now in the midst of a major data encryption process for its computers, its systems, and any media associated with the use of public health information. And so that will be rolling out this year also.

We also know that capacity-wise, that you're going to see today that the amount of data the Agency is going to use is going to multiply significantly. And so we have to have servers and systems that are able to handle that capacity. We're in the process of moving a number of our data systems to data centers which will provide that 24/7 maintenance capability as well as be much more able to handle the massive amount of data that's coming in.

And I think it's also important to note

that in order to run a public health system, you have to have what we call a fail safe capability which means if the primary application goes down, you have to have the secondary system ready to turn right on so you don't lose a step or beat in the process. And we're in the process today of building that fail-safe capability also.

So we feel that our information technology and infrastructure will be in place to carry out this system.

The last principle was fully implement management controls so you can measure organizational performance of the program at all levels of the organization and then hold management and supervisory personnel accountable for development of inspection method, training, processes and implementation of corrective measures, and the Agency again takes this guidance very seriously. The Agency has implemented management control across all eight program areas, and we are automating that process also so that it triggers in organizational performance, will be flagged to the managers or responsible supervisors so

they can react to that.

And then what's key is also being able to document that you follow up when you find organizational performance that's not meeting expectations, and that's a key component of this system also.

So in conclusion here then, FSIS has reached management agreement with the Office of Inspector General, on their 35 recommendations and I believe you'll see in the next 2 days here how those guiding principles have been included into developing the Public Health Risk-Based Inspection System.

So are we going to take questions?

MR. TYNAN: We can take just a couple of minutes to ask any questions of Mr. Smith if there are any from the Committee? Mr. Kowalcyk?

MR. KOWALCYK: Yes. Thank you. In FSIS' review of OIG's recommendations with respect to the data infrastructure, what has the Agency done in a way to get a handle on how the end users will interact with this system? Are there any constraints

that just because of where the inspectors are out in the field that would make data entry not as timely as you would like? Are you looking into ways to, working in those environments where they're out of a slaughter or processing facility that's way out, far away from wireless or broadband activity?

MR. SMITH: The Agency has over the last years launched a major initiative to get high speed connectivity to the entire field, and we have in all but I believe at this point 51 locations accomplished that goal. This system will be a web-based system. That differs from what we have today because we have what we call is a client server system, and so the database actually resides on each inspector's computer and then requires a lot of transmission of data back and forth in order to update the servers here. That becomes a security issue also trying to keep 4,000 computers current and the most current information on each computer. By changing to a web-based application, then everything's on the servers, the security is on the servers, and we do recognize that there will be times when inspectors will be

offline and so we will build a capacity into the inspector's system so that the data they collect when they're offline will be accumulated until they hook up to the server and then transmit that information.

As I said, by April, we will have high-speed connectivity to all assignments within the country and we're only missing 40 out of the assignments we have today that have not had that high-speed connectivity. And the reason that is because we're putting UTN lines in and we have to actually run those lines in. Everywhere else we either use satellite, DSL or EVDO technology.

MR. TYNAN: Mr. Painter, we're going to let you have the last word on this period.

MR. PAINTER: I'd like to make a comment on -- Stan Painter, National Joint Council -- on what Bill said regarding the Internet connection. In the cases that I'm aware of, the satellite which is supposed to be much faster and much more efficient is slower and less efficient than the dial up that the inspectors had and the supervisors had in the field. Actually, people are actually disconnecting from the

satellite and plugging back into dial up to have a more effective system in a lot of cases. So I'm wondering in those cases where you don't have DSL and you do not have some kind of wireless other than satellite through Verizon or something of that nature, what's being done, if anything, to speed up the satellite system?

MR. SMITH: FSIS has approximately 640 connections on the satellite, and we track that very closely through our help desk, and so we know the amount of traffic coming in about issues with the satellite, and we're documenting those. Since -- in the last 6 months, we've had approximately 300 inquiries into our system, and we're able to turn around and work with those.

As new technologies come on, we will be moving away from the satellite because of encryption issues that we'll have in the future. When we do track specifics, we're able to help those folks. We have yet to find a location where we have a slower speed than dial up because not every dial up in those locations were under 56K either. So it's comparable

and the advantage, while not perfect, the advantage to being on the online is the satellite is they're connected 24/7 as opposed to dial up.

So I'll be glad to discuss any of that further but we understand there's problems with the satellites. We're working with the satellite industry. We have increased bandwidth from the day we started with satellite six times, and we are continually working with that vendor.

MR. TYNAN: Mr. Painter, I know you have a follow up question, but I'm going to ask you to hold the question until we get to the full, full discussion. It'll be a little while, but hold your question. We don't want to deter you from having it, asking it. It's just in the interest of time, so we can do it in the larger group session.

I'm going to introduce Dr. Carol Maczka so that she can do an overview of the rest of our session.

DR. MACZKA: Thank you, Robert. I'm going to talk a little bit, an overview of the proposed Public Health Risk-Based Inspection System for

processing and slaughter, and you'll be hearing a lot more of the details as we go through the rest of the day. So again, this is just an overview.

So where are we today? Well, we think we've evolved since we presented on RBI last year. We have examined and are in the process of improving every aspect of our system. We believe what we've moved towards is more of a public health based data driven approach, and all of the impetus for this has been concomitantly received, even from USDA, OIG, from consumer groups or industry.

So today what we're looking for is your technical input into what this proposed draft concept and again, like Dr. Raymond said, this is very much a draft concept, and we can't emphasize that enough. Your comments are critical to us in the next two days and comments we receive from the public also.

So what's the goal of this proposed new system? It's to focus inspection activities on those points that are considered vulnerable in the food safety system, and you can see that really fell out of one of the OIG comments that Bill went over.

We also want to make sure that we prioritize our deployable resources to establishments where we feel there is a lack of process control. And what we're talking about here is deploying our EIAOs and PHBs to those establishments where we believe there's a lack of process control to conduct FSAs and IVTs and in depth verification testing. We believe that what we are proposing is resource neutral.

So what are the components of this new system? It basically has two major components. The first is a algorithm to allocate resources across plans, and then once we do that, you think, well, what will you do you're inside of the plant? And so the second part of this approach is an approach to focus inspection activities at vulnerable points within an establishment.

And what do we mean by vulnerable points? Well, that's where you have the greatest microbial contamination or growth if process control is not maintained.

Okay. So this slide tries to bring the two

components of the system together the levels of inspection and it also brings the within plant activities. And what you see is we take the establishments and based upon factors that we believe indicate process control, we divide them up into three levels of inspection, LOI 1, 2 and 3, and then Level 2, we further rank in terms of potential public health impact, and we're going to go into more detail, what that means but basically the factors that come into play here is the fraction of volume that an establishment is producing for that particular product based upon the national volume for that product, as well as the attribution of that product to the illness, public health illness.

So what are the three levels of inspection? We have routine inspection. That's LOI 1, and that's where we're going to have for cause procedures, and what do we mean by that?

Well, let's take poultry slaughter. If at the end of the line we see there's feces on a bird, or if we see generic *E. coli* or maybe *Salmonella* is, for a lack of a better term, out of whack, we're

going to send the inspector up the line to look at vulnerable points in the process and to answer certain questions, yes/no questions, that relate to whether there are controls in place and whether those controls have been implemented. So that's what we mean by for cause procedures.

Under LOI 2, we're going to have both for cause procedures and directed procedures. By the virtue of the fact that you're in LOI 2, we feel that there is more inspection needed, and so in addition to the for cause, we're going to have directed procedures.

In LOI 3, this is where we have in depth inspection, and this is where we have not only for cause and directed procedures, but this is where we're also going to send deployable resources to conduct FSAs and IVTs.

Now what do we mean for cause and directed procedures, and I'm going to kind of read through this with you. So, if an inspector -- in the first box, if an inspector is performing a procedure as part of his normal or routine inspection activities,

if he finds that there's a noncompliance, he's going to be asked to document that NR and to verify that corrective action has been taken. He's going to record that in the new Public Health Information System. And then some time may pass, like a week or so, but based upon that NR or repetitive NRs or information from the profile, which Charlie Gioglio will talk about next, that combination of information will cause a for cause procedure to be generated and it will tell our inspector to move up the line, look at certain vulnerable points, answer certain yes/no questions, as to whether there are controls in place, and whether they've been implemented. So it's a very simplified version of what would happen and again we'll go into more detail about this in about two more presentations.

As we talk about these levels of inspection, and you're probably interested in, well, how do you get into a LOI 1, 2 or 3. We're going to go into the criteria. Curtis Travis will go into the criteria for those different levels but basically the idea is you'll either be sorted into LOI 3 or LOI 1,

and if you don't fall into either one of those, you're going to end up in LOI 2, and then you'll be ranked based upon your contribution to public health.

So what's going to follow? First, we're going to hear from Mr. Charles Gioglio. He's going to talk about the Public Health Information System and how it actually incorporates what I just described. We're also going to go into detail about for cause and directed procedures, and we're going to tell you a little bit about the criteria, a lot about the criteria, of placing you into the different levels of inspection and what we hope to do is provide you with some case studies for instance, talks, of some other things we've recently had to deal with, and demonstrate how this proposed system would help prevent the problems that occur in those kind of situations. So we'll present two case studies.

So the benefits of the proposed system, what do we think they are?

I'm going to go through a list, and then I'm going to ask that you keep this list in mind as

we go through the next two days and see if you believe we've actually accomplished what we set out to do.

One of the benefits is that we think we've moved now to a more data driven, science based framework that operates within our current regulatory framework, our current HACCP, SSOPs and SPS framework.

We believe that it will enable our inspection force to link and respond to noncompliances.

We think it will ensure that inspectors will verify the execution of decisions made by the establishments with respect to their hazard analysis and prerequisite programs.

We believe it will focus on pathogen-product pairs that most contribute to disease.

We believe the approach now is much more transparent, that all high pathogen failure plants will be ranked high, that public health-related NRs that are in the top percentile are ranked high. Now we believe that there will be a lot of controversy on

this point, and we're very interested in your comments as we move along.

We believe that we've moved away from categorization, that it is independent of production volume, so that we do not believe we need to use the Nona Compromise that was developed, that we've actually fixed this problem.

We also believe, and it's not shown up here, that we moved away from the concern of how we're going to weigh factors, what was the weightings that we were going to assign and how we were going to justify those. The factors that we're using will be treated independently. So we think that's how we solved that problem.

And we think that what we are proposing is compatible with current sampling programs.

Finally, we believe that the information that's collected in aggregate at these vulnerable points, will provide further regulatory support for enforcement actions or regulatory actions.

So again, we want you to keep these benefits of the system in mind as we go through the

next two days and really comment on whether we've accomplished what we've set out to do.

Dr. Raymond mentioned that there is a timeline and I believe Carol Tucker-Foreman originally asked for this, but we have actually developed a timeline for the development of this proposed system for the public health based inspection system which Charlie Gioglio will talk about next and for the poultry slaughter rule. And we will be happy to show you this draft timeline, at least what we're planning on operating on. We realize that we may get a lot of comments that may make this timeline have to be adjusted but this is currently what we're currently proposing to follow up and we'll be happy to distribute that.

And I think what I'm supposed to do is introduce Charlie Gioglio now to talk about the Public Health Information System, and then we'll take questions and comments after that.

DR. GIOGLIO: Thank you, Carol. While we're getting the presentation put up on the screen, I just wanted to say what I'm going to provide is an

overview of the Public Health Information System that Bill mentioned and Carol mentioned, and get into a little bit more detail about the domestic inspection function of that system.

The domestic inspection function can be thought of as, in essence, I think about it as a replacement for the PBIS system, the Performance Based Inspection System, but actually it is more than that that we're developing now. Presently we're working with a contractor to work through the specific requirements for the system that the contractor will then go and build for us and then we'll conduct the testing and so forth as Bill mentioned. We're aiming at having requirements from the contractor by the end of March this year, that we can sign off on and then the contractor can go out and build and we can follow through then with our draft timeline to do the testing in the field and so forth that we need to do.

To go back, the system itself has four main components, and that is as I mentioned, the domestic inspection system or the replacement of PBIS. We

intend to automate the import inspection function, automate the export certification function in the field as performed by our inspectors, and then we'll have a predictive analytics function that you're going to hear more about I think later.

I will say that it's expected that the system will be employed across all establishments and all facilities where we have inspection coverage. In other words, both slaughtering and processing establishments, okay, anyplace where HACCP plans are required, as well as at official import inspection facilities or even ID warehouses and so forth.

Okay. So the domestic inspection function is as I mentioned, the replacement for the PBIS but it will be a new application that will help us achieve some of the strategic initiatives that Bill discussed earlier that we're going to hear a little bit more about later.

What we're working through is the system for collecting detailed information regarding the verification activities that happen in the plants, compliance with specific establishments, and any

other inspection related activities.

The system is being designed to facilitate the analysis of specific data across all levels of the Agency. So in other words, Headquarters policy analysts would have access to the data, folks in the District Office as well as down, in fact, to the inspector level or when we're planning for food safety assessments in the field and so forth.

The whole point is to be able to identify trends, okay, to evaluate those trends, so that we can get in front of where problems may occur, to focus our inspection activities in plants and on points where either they may be vulnerable to microbiological contamination based on the data that we collected and analyzed or where process control is not maintained.

The new system will incorporate, as I mentioned earlier, food safety assessments or the FSAs, okay. It incorporates a recording instrument that will integrate the data from those FSAs, okay, and other activities that the EIAOs perform with other Agency data. Some of you here on the panel, in

fact, I know are familiar with some of the FSA reports that our folks do, and they could be at times upwards of, you know, 100 pages of prose and there's not necessarily any specific format. It makes it difficult for our folks in the districts to at times analyze those reports as well as if we want to analyze those reports across let's say a segment of the industry or in a given district or so forth. It makes that type of analysis difficult.

The system is being designed to make those types of analyses of those data easier to deal with so that, in fact, we can pull out the trends, do that instead of as Bill mentioned, do the data mining by hand and have people in the District Offices do that data mining, allow the system to help us do it.

The system would also be utilized to prioritize deployable FSIS resources, okay, to focus on establishments with evidence of lack of process control. When we use the term here, when I use the term deployable resources, what I'm meaning are the FSAs that are conducted by the EIAOs, directed sampling activities and so forth, okay, not

necessarily moving inspectors from one plant to another but, but focus on those deployable resources, resources that we could much more easily move to the places where they are, in fact, needed.

The system will provide a more user friendly, web-based, as was discussed a little bit earlier, interface for inspection teams supplying data on procedures, inspection results, sample requests and results, the food safety assessments and the enforcement status of any given establishment. The information would be much more readily available through, without getting into too much of the design of the system itself, through almost like we could think about it as a whole page for that given inspection assignment or that given inspection team, where that information, because it's a web-based design, would be much more readily available for those folks or the people in the field so that they can go ahead and plan their days appropriately and know then where to focus.

An important thing to remember here also is we're working to integrate this system seamlessly

with our other existing and planned systems, okay, permitting the users in the field as well as other analysts to use that data, okay, and to analyze the data from multiple programs or, in fact, from different systems within the Agency. Presently we do have, because we're working oftentimes, and PBIS is late 1980s technology that that's based on, and some of the programs are a little bit newer than that, but we are moving ahead rapidly with this system. The idea is to eliminate the stovepipe systems that we have across the Agency so that replacement system for the PBIS will communicate effectively through the data warehouse with what information we have on let's say imports that may be happening or exports that took place at a given establishment, for example, with the FSA data, with the laboratory certainly sampling data. Presently, we need to have analysts that actually pull those things together, okay, or have to work to do programming to integrate those data so that they can be analyzed. This system is being designed to facilitate that type of analysis.

If we just focus on replacement for the

PBIS, the system will document specific procedures with regard to the product categories, the regulatory requirements that were set out to be verified and then those that, if there were noncompliances found, those that were, in fact, found noncompliant for that particular procedure that was performed, and the method of verification used. The system will provide a lot more information in this area, in the way of its being designed with not a lot more burden for the inspector. In essence, what we talked about within our workgroups is that we are setting out to automate the system that the inspectors have been employing, if they're following the training that they've been provided through the FSRE training and so forth, they're going through these calculations as it were and making these decisions on a daily basis.

They're going through the calculations in their head, and they have not necessarily documented or documented in an analyzable way. This system will, in fact, provide that tool then for the inspectors at the plant level as well as then for our analysts across the Agency to be able to document

those and then to be able to utilize to direct as we talked about, as Carol just touched on, to direct the follow up or for cause inspection activities where they need to be performed.

Key benefits include the ability to use data, as I mentioned, and the ability to provide data to enhance management controls in identifying trends. So this system will work together, as I mentioned earlier, with the other Agency systems, the assurance in that system which is the system employed by field managers for management controls.

I probably didn't go into any detail earlier, but on the first slide, we broke down the domestic inspection function here actually into three parts. One is the establishment profile, the actual in-plant inspection activities and the FSA component. The establishment profile will provide enhanced operational information regarding the establishments such as the types of interventions used at the given establishment, and the specific products that may be produced at the establishment.

The enhanced demographic information such

as the processing activities that they employ were product volume, food defense activities that we presently have incorporated into our PBIS system, in order to inform product sampling programs and directed inspection activities.

Lastly, one of the key enhancements over the PBIS is that the system will provide the ability to document and maintain forms such as the Memoranda of Interview, that the inspectors use presently with their weekly meetings with establishment management as well as if there were any food defense vulnerabilities that are identified by the inspector as they are working through food defense procedures. Those forms, 5420-1 and 5420-4, are what's used in the domestic establishments and then at the import facilities.

Those, we're working to actually automate those so that the inspector would input the data into the system and then the system itself can generate the forms and/or the memos based on the input that the inspector has put in, the data the inspector has put in.

And then on the other side, the new FSAs will have questions associated with them to allow the analysis of the data and not have to have analysts work through a 100-page document and possibly miss something, to work through, so that the correct pieces of information are being collected in an analyzable way. This structure will facilitate then we think the critical thinking on both the EIAOs but also allow for the additional analysis.

MR. TYNAN: Are there questions from the Committee regarding either Dr. Maczka's presentation or Mr. Gioglio's? And I'll take questions here, and then I'll ask Mrs. Foreman and Dr. Cutter if she's been able to participate to raise a question. And it looks like this has been an interesting topic. Mr. Elfering, I think you were up first.

MR. ELFERING: Yes, this is Kevin Elfering. I think one of the things that I really think we need to concentrate on, in looking over these documents, and I realize this is more of an overview right now, and a lot of draft, but I think we should really be concentrating more with our current and true and

public health risks.

In reading some of these documents, there's discussions about trichinella spiralis. There's talk about SRM removal because of bovine spongiform encephalopathy and, you know, I know that those are issues but I think they're probably more trade issues than they are truly public health issues. And I think we should be concentrating more on things like *Salmonella, Listeria monocytogenes, E. coli* and things that are truly a public health risk.

Even in the poultry slaughter document, it discusses about SRM removal. I mean, I would have to ask some of the poultry experts, but I don't know if there's any mad chicken disease.

(Laughter.)

MR. ELFERING: So, I mean, I think we have to concentrate on things that are truly public health risks. I understand that mad cow disease is certainly an issue, but it's not to me a public health issue. I think we really need to concentrate on those.

MR. TYNAN: Thank you. Did you want to

comment, Carol?

DR. MACZKA: I think when we go to the tables that we call the prompt tables and the for cause and directed procedures, you'll see that I think that emphasis is there on things like *Salmonella,* generic *E. coli* and indicator process control, other things that are really public health related, and the thing about SRMs and chicken, that is a mistake. So I think you'll see that as we go along.

MR. TYNAN: Okay. Dr. Bratcher.

DR. BRATCHER: First of all, I have seen a couple of mad turkeys but (laughter) but not chickens.

MR. TYNAN: Hopefully not this morning.

DR. BRATCHER: Exactly. The question that I have is, and I assume that probably this has been addressed, but there's always a training component that's necessary anytime you're doing an evolution or a transition to a new type of inspection or a new process. And I would like to remind you that there needs to be a needs assessment and a curriculum

review, pretty much of what the FSRE program is and what other things that we need to be doing. And if we're going to be asking some of these people to perform some new tasks, we need to know what they need to perform, the task or function, and then the new environment that we're going to be doing. What is their present functional level and any of the people in here that have been supervisors, and I know that there are varying degrees of levels of functionability between the inspection workforce that we have out there today and also with the veterinarians that we have in the field today.

And so that would bring up pre-assessment basically where you would assess the functionability, look at the training and educational needs of the workforce and then after you have done that, I would like to remind you that you need to do a post-assessment and reevaluation of your training and whether the people are able to do what they're being asked to do.

The other thing that is kind of interesting, and I tried to go through a lot of the

material, we're moving to a new science-based form of inspection, and the National Association of Federal Veterinarians has been in favor of doing that for years, and we've been a real proponent of that. We've been a proponent of doing the risk-based inspection methodology and for removing the veterinarian from doing some of the tasks, and I think Dr. Raymond's referred to this many times, that it's not a real good utilization of resources if you have veterinarians giving breaks on the poultry line, and if you have people that are tied to the line when there are other tasks that need to be done and you're short-staffed. So we're very much in favor of that.

And there was a task force of veterinarians I think in 2001, a report, also pointed out the importance of a system like the PHIS, and I'm very glad to see that we're doing those things as well. But if we truly are moving into a new science-based inspection system, I would hope that we would look at this not just as an evolutionary process but maybe a revolutionary process because the industry is making significant changes and doing a lot of things that

are much different today than what they've been doing in the past and given the ability to do things, I think that they can move this process much further forward than what we're even looking at maybe in this room today.

MR. TYNAN: Dr. Bratcher, not to interrupt, but that's -- is there a question there because what we're going to use this time for is clarification. So not to cut you off. I think all the points you're making are important, but if there's a question, we need to get it out on the table, or I'll ask you to hold that maybe until the --

DR. BRATCHER: The question is there are no educational requirements for any of the positions in FSIS today with the exception of the PHBs that are in the in-plant positions and the DVMs that are in the District Offices, and I would, I would like to know if the Agency has thought about the educational requirements that need to be in place for CSIs, EIAOs, FLSs, DDMs, DMs, and all the way up through the chain of command?

MR. TYNAN: Okay. Thank you, Dr. Bratcher.

I'm going to let Carol or Mr. Smith address that, and then perhaps either during the open discussion, we have Dr. Karlease Kelly here who is the head of our Office of Outreach, Education and Employee Training, and she may be able to address some of those issues as well. So we'll sort of loop back.

MR. SMITH: Just real quick. We agree that an assessment needs to be done. There is an educational requirement for the EIAOs, and the requirements phase, once we go through this developmental and this continuous input into developing this, once we get our requirements, then we can develop our policy and then we can do, and I agree with you, we need a skills assessment on who's going to do what and then how we train people. I fully agree with you.

MR. TYNAN: Okay. Mrs. Foreman, are you on the line? Do you have a comment? I know we can't see a tent card up. So --

MS. TUCKER-FOREMAN: Can you hear me okay now?

MR. TYNAN: Yes, you're breaking up just a

little bit, but go ahead and give it a try.

MS. TUCKER-FOREMAN: Okay. It took me a while to get on. I -- at all. I do have a question about information -- the OIG Report. Now that the Agency has reached management agreement -- on all of the -- the Agency has reached management agreement -- and, in fact, the OIG audit -- supposed to be carried out -- after the agreement -- latest, and yet --

MR. TYNAN: You're breaking up a little bit, Carol.

MS. TUCKER-FOREMAN: And on page 38 of the Report -- being able to get information -- recommendations and -- management agreement but nothing has happened. So how does the Agency -- this time to make sure specifically on information technology -- agreed to with OIG --

MR. TYNAN: Okay. Mrs. Foreman, if I understand your question, it has to do with how we're going to assure this time with the OIG that the IT issues actually happened. Is that correct?

MS. TUCKER-FOREMAN: That's correct.

MR. TYNAN: Okay. Fine. I'm going to let

Mr. Smith respond to that question.

MR. SMITH: Yes, thank you for your question. A couple of things. We are putting in place an automated tracking system as another program that's in OPEER, that will be tracking each and every one of these recommendations and their due date and how we're progressing along and, in fact, we have already issued interim reports on some of the recommendations especially in the IT. So we've already put that in place. So we will hold ourselves accountable to doing that.

MR. TYNAN: Were you able to hear the response, Carol?

MS. FOREMAN-TUCKER: Yes. Thank you.

MR. TYNAN: Okay. I'm going to go to Mr. Covington. I'm going to let him have a question, Dr. Henry, and then we're going to perhaps take a quick break. I think we're a little bit ahead of schedule, which is good.

MR. COVINGTON: Thank you. Brian Covington. Carol, you mentioned the timeline associated with the progress and implementation of

the PHIS system. Is that timeline the one that's consistent in the OIG Report?

DR. MACZKA: Yes, it is, and it's not just the PHIS, but also the system that we're describing here today as well as the poultry slaughter and we'll be happy to, as I said, give you a copy of this draft timeline which is subject to change.

MR. TYNAN: And we'll have the timeline -- we'll pass it out during the break and have extra copies out on the table outside for the public that is interested. Dr. Henry.

MS. TUCKER-FOREMAN: Will you have one e-mailed to me?

MR. TYNAN: We will. Yes, we will do that. And we will try and do it as soon as we can.

Okay. Dr. Henry, please.

DR. HENRY: Thank you, Robert. Quick question, Charlie. Relative to the PHIS system, it appears to be such an advancement beyond PBIS, and with the implication it has for the new risk-based, you know, public health system, do you foresee a phase in period to establish baseline data to all

plants because you have a lot of different points that the inspectors would react to, the profiling that needs to be done, et cetera. So how does that fit in, and is that built into your timeline? Thank you.

MR. GIOGLIO: In fact, that is built into the timeline, the draft that we have. We actually are -- presently we're concentrating on setting the requirements for the system and design of the system and so forth, and we have begun discussion about how, in fact, we will do both things, both implement the system in the most effective way that we can across the country as well as get our inspectors and others across the Agency trained appropriately.

So we haven't made any decisions along those lines exactly about how we're going to implement yet but, you know, we recognize that we have some options there and we do need to work through, and I expect that to be, you know, likely -- this entire process --

MR. SMITH: I just want to add real quick. We have agreed with the Office of the Inspector

General on how we will perform and where we will perform food safety assessments prior to the implementation and, two, the other piece about the data integration where we said we had that in the statistical basis for our windows and frames and decisions, Carol and her folks will be presenting that later and will be open to discussion and those we'll set pretty much the baseline that you're asking about, and you'll be fully aware of those before any implementation.

MR. TYNAN: Okay. One last question from the Committee.

(No response.)

MR. TYNAN: Okay. There being none, I'm going to suggest, we're just a little bit a head of schedule, but I think we're going to need that time this afternoon. So, if it's agreeable to everyone, I'm going to suggest that we take a break now rather than a little bit later. I'd like you to come back at 10:00, and in the meantime, we'll change presenters and try and get the timeline available for you.

(Off the record.)

(On the record.)

MR. TYNAN: Can I ask everybody to take their seats again please?

(Pause.)

MR. TYNAN: If everybody's ready, we're going to get started on the second part of our morning agenda.

I'm going to invite, Mrs. Foreman, if you're near a computer, if you have some issues with getting a question to us, you want to send me an e-mail I will try and read the question. We are having just a little bit of difficulty hearing you with your phone. It's breaking up, and we want to be sure that you have an opportunity to ask the questions or make the comments that you would like. So I will invite you to do that.

MS. TUCKER-FOREMAN: Hello. Hello. What I'd like to suggest is let me try using it without the earpiece one minute if you would. Hello.

MR. TYNAN: You sound good. We can hear you now.

MS. TUCKER-FOREMAN: You can hear me?

MR. TYNAN: Yes. Very clear.

MS. TUCKER-FOREMAN: I've still got the ear piece on. I don't know what the problem was before.

MR. TYNAN: Well, if you start to break up, as I say, you can send me an e-mail, and I will try and reflect your question as accurately as I can.

This morning, we talked, we gave some overview presentations. Now we'd like to get into a little bit more of the detail. I have Dr. Erin Dreyling, who is a data analyst with our Office of Food Defense and Emergency Response, and she's going to give a little bit of discussion, a more detailed discussion about the within establishment inspection concept, and then we'll have Dr. Arnold who will give a case study. And with that, I'll turn it over to Dr. Dreyling.

DR. DREYLING: Thank you, Robert. Good morning to everyone.

As Robert said, what I'd first like to do is to go over more of the details of the within establishment Public Health Risk-Based Inspection

System for both processing and slaughter establishments. And I'm going to give you an overview, and then my colleague, Dr. Arnold, is going to provide you an example of how this system would be implemented for a specific product category. And what she's also going to do is to go over a case study with you. She's going to talk about Topps and give you an idea of how we feel the proposed system would have addressed the problems we have encountered in this situation.

So with that, as you've heard already this morning, the within establishment system is designed to focus our inspection activities on vulnerable points within an establishment. And when we're talking about a vulnerable point, what we're talking about is a point within the establishment that has the potential for the greatest microbial contamination or growth if process control is not maintained.

So how will this play out in the new system?

Inspectors will carry out their existing

inspection activities, such as for HACCP or SSOPs, and when prompted by the new Public Health Inspection System, they will go to vulnerable points, and they will answer questions about those vulnerable points. And I want to make a few points here.

One is that the prompts I am talking about will be built into the Public Health Inspection System. The inspector will not have to notice that a certain NR has been recorded or that a certain profile change has occurred. The system will be monitoring his recorded NRs and changes in the profile information, and if a certain signal occurs and these are things that are public health based, such as sanitation NRs or a change in your HACCP plan, these are things that the system will have built into it, and it will prompt the inspector to then carry out this procedure where he looks at vulnerable points and answers questions.

And these prompts and the questions are all specific to the nine HACCP categories that FSIS has designated. And each specific product category has its own prompts and each prompt has its own

designated vulnerable points and questions that are associated with it. And we are going to go through an example of the prompts and the questions as we move forward today.

The next thing I want to point out is that observations that the inspector makes at these vulnerable points is not intended that if you get -- these are yes/no questions. And it is not intended that if you get a no, that you will get a NR. It is the aggregate observation of those points that will allow the inspector to decide whether or not compliance is present. And we feel that this will also add some additional support for enforcement actions when appropriate.

And I want to point out here that the things that the inspector will be looking for, the vulnerable points, we will be developing compliance guidelines that will be posted on the web and that industry and consumers will have the opportunity to comment on. So we will be interacting with industry as we develop these, and we are doing this within our existing regulatory framework. This is not any

additional layers of regulations for industry.

And I want to also as we've already had the question this morning, point out that we are working closely with the training part of FSIS, and we have already begun our discussions on developing the training that will be necessary to implement this system, and for the inspectors to understand how to make observations at vulnerable points and what to do with that information.

I just want to give you a brief overview. This lays out how within establishment inspection will work in our new Public Health Information System.

First, as you can see, the inspector will perform a procedure as part of their routine activities in an establishment. If they find a noncompliance, they will document it and they will verify that corrective actions have been taken, and they will record their noncompliance report in the new Public Health Information System.

And then as I was saying, the Public Health Information System will be monitoring NRs that are

recorded or groups of NRs that are recorded or changes in profile information and when appropriate, it will issue a for cause procedure that the inspector will carry out. And when he carries out that for cause procedure, he will be looking at the vulnerable points and answering the questions that are appropriate for those points. And those are specific to each of the nine HACCP product categories.

The inspector will record his response to the questions in the new Public Health Information System and they are yes/no questions and they will also have the ability to say not applicable because some of the questions may not be applicable for a certain establishment given their circumstances that they're working under.

And I do want to point out that we've already alluded to this, this morning, that certain levels of inspection, if you are in the middle category or the highest category for inspection, you will be having what we're calling directed procedures. And this will be having the inspector go

to the vulnerable points and answer questions but a prompt will not be necessary. We feel that if you are in the middle or the highest category, there is an indication that you do not have process control, and we have reason to believe that we should be looking at your system to ensure that process control is being maintained. So we will have directed procedures at a frequency that the Agency will determine where the inspector will go to vulnerable points and answer the questions.

I want point out that this goes along with the OIG request that the system should be data driven and science based. We have developed this proposed within establishment system. Based upon the scientific literature, we have identified the vulnerable points from the scientific literature and also used the literature to inform the questions that we've developed for inspectors.

Also, this is based heavily upon our past experiences with HACCP and contamination events, and importantly, also we have gathered FSIS experts for policy and from the field and from training and we

have had them sit down in the room and develop the prompts and the questions that are in this proposed system.

I want to go over briefly the benefits that we see for the proposed within establishment system and then my colleague, Dr. Arnold, is going to give you a real life example to really show you how we feel these benefits would play out.

First, as we've already discussed, this system is designed to focus on the identification of vulnerabilities within the overall food safety system, and we feel that we will be doing this by helping inspectors to verify that establishments are carrying out the decisions that they have made in their hazard analysis such as the implementation of prerequisite programs.

And, we also feel that this system is designed to help establishments to link and respond to noncompliances and to verify that corrective actions are fully carried out by the establishments.

And as we've already discussed, the inspection results are going to be automatically

monitored by the public health information system, and it will be detecting anomalies and therefore it will be prompting inspectors to respond to these anomalies and to examine vulnerable points within the establishment.

So I'm going to turn this over now to Dr. Arnold, and she is going to go through one of the prompt examples that I've talked about. So this is an example for a fully cooked, not shelf-stable product, and she's going to go through the prompt and the vulnerable points that have been identified for it and also the questions that the inspector would answer when he or she went to look at those vulnerable points.

DR. ARNOLD: Thank you. Good morning. The example that I'm going to give you, we had developed associated with as Erin said the fully cooked, not shelf-stable product, and as a result, as you've already heard this morning of the OIG audit, regarding the issues impacting the development of RBI of meat and poultry processing establishments. We kept in mind what we need to do as far as moving

forward and evolving into the next steps in the implementation of HACCP. It's been a long process and the last time I was here, I spoke to you about the implementation of HACCP. So now I'm here talking to you about the implementation of the Public Health Risk-Based Inspection System.

And, we were guided by the OIG audit in our decisions and development of the process, and we looked at the different processes and tried to think about what might be appropriate prompts in the particular process where we could look at, as Carol mentioned, issues where we might have excessive microbiological outgrowth if these points were not controlled. And it's not that they're CCPs.

So the prompt description here is product temperature not controlled by the CCP throughout the process, and in many HACCP plans for fully cooked not shelf-stable products, companies have control points for the temperature controls in storages. They do not have CCPs for the temperature controls in certain steps. So this is one of the vulnerable points that we identified.

And the threshold, what we would be looking at is two or more observations associated with temperature problems, with noncompliances associated with 03G01, and this is just one possible example of a prompt in fully cooked. There's several other ones. So I just wanted to mention that isn't just one prompt.

When we looked at the vulnerable points, we looked at what would be expected as a control point in the process. We tried to look at process control in a fully cooked, not shelf-stable process. We identified receiving and storage, processing which could encompass many different components and then storage and shipping as the vulnerable points in that process. Utilizing as, Charlie Gioglio had talked about this, this morning, the enhanced establishment profile information, the Public Health Inspection System. We are going to know certain information about that establishment and certain programs that they may have, requisite programs or controls in place, and using that information, will then drive us to certain questions that the inspection personnel

will be asking themselves and looking for either a yes, that's great, let's move onto the next thing, or no, do we have an issue here or not, is the process in control or not in control or not applicable.

So as you see here, at the receiving and storage vulnerable point, we have questions like does the establishment have measures to ensure materials received are wholesome and safe? Yes or no. Are control measures being implemented? So we're looking at the control measures as Carol indicated earlier. Are they being implemented? You know, when they say that it's not reasonably likely to occur because we have this prerequisite program in place, are they actually implementing what they indicated they would implement?

Does the plant have controls on incoming amounts of microbes on the product or adjust their processes according to incoming loads? We know that many companies test their product and evaluate incoming product and have purchase specifications associated with that product. And we want to know, are the controls being implemented? It's just a

simple yes or no.

And the next is does the establishment have appropriate controls for returned products? We know that in a lot of plants this is another issue, returned products, how they handle those returned products, what they do to those returned products, whether they accept the returned products. Yes or no. And then are controls being implemented?

And the last question relates directly to the prompt that I reviewed, does the establish monitor product temperatures during storage?

So those would basically be some of the questions that the inspector would be prompted to think about when there is identified a problem in that process.

The next vulnerable point was the processing step, and once again, utilizing the enhanced establishment profile from the Public Health Inspection System, we are going to focus on certain questions based on that profile of information and the first question is, if not a CCP, does the plant achieve sufficient lethality?

We know a lot of processes that may identify a CCP, such as water activity, but they do have a lethality step that may not be a CCP. So, if they do have that, we're wanting to know whether the lethality was achieved and whether it was sufficient or not. Once again, we'll be using the information in that enhanced profile to know whether that would be an appropriate question to ask at this establishment.

Is rework and carryover addressed in the hazard analysis? Again, we know that that's a problem, depending on whether the answer is yes or no or hopefully not applicable. Where we evaluate that information in the system would be able to look at those things.

Does the plant have controls in place to ensure cross contamination including different species does not occur? Are controls being implemented?

Once again, go back to that, you know, are we seeing the controls and are they being implemented.

Does the establishment have proper procedures to follow up positive *Lm* results on food contact surfaces or environmental samples? Yes or no. And is the plant carrying out follow up procedures? When they have that positive on food contact surface, what are they doing? Yes or no. Do they do something?

And then are the establishments under Alternative II or III, we're focusing on Alternative II and Alternative III that are using sanitation programs adequately implementing the program and controls? So we're not actually looking at necessarily sanitation SOPs. What we're looking at is what's spelled out in Part 430 of the requirements for those establishments operating under those specific alternatives.

And then last is, has the establishment undergone recent construction, and if so, has it increased *Lm* monitoring? And do records show increase in *Lm* in the environment?

So those would be the basic questions, yes, no, or not applicable that would give us more

information for the system.

As Carol indicated, this is going to be data driven. It's going to be science based, and it's going to look at what we currently have and then enhance that.

And then the last vulnerable point is storage and receiving, and we're going to ask the question, does the establishment have verifiable temperature controls in the storage? We know at least in those establishments that have post-lethality exposed product, if they do have contamination with *Listeria monocytogenes*, that if they're not controlling the temperature, that has an added component in the there that once again the process is not under control.

Does the establishment monitor conditions in storage areas that would cause adulteration of the produce, such as over spray, dripping water, et cetera? So once again, a lot of companies have these control points in place and so we're just looking at those control points to make sure that the overall process, we're moving more towards the systematic

approach to inspection. It's kind of like anyone who has children, you know, connect the dots. They have dots, they connect them, and that's what we're doing now. We're going to be connecting those dots, moving forward to help inspection personnel understand this has to be a system approach to how we evaluate that.

And then the potential regulatory outcomes, we've identified in the process different outcomes depending upon what may occur in that particular system, based on all the feedback and information that we gather on the system. A good example is when they have a process control as a CCP and their hazard analysis decisions are not supported, which you will see in the case that I'm going to present for you next, and we're looking at those and in particular control of *Lm* in post-lethality exposed ready-to-eat product. So those were a few of the possible outcomes.

Now I'd like to move on at this point to our case study and we're going to be talking about Topps Meat Company, and the multistate outbreak of *E. coli* O157:H7. And we know that there originally was

a food safety assessment in October of 2005 as a direct result of an illness that was reported in a child, and that that assessment resulted in the establishment's reassessment of their raw ground HACCP plan and the reevaluation of their prerequisite program. They had been issued a noncompliance at that time of the FSA for failure of the prerequisite program purchase specifications.

And the other thing that happened about the same time was that the company also got new management. So there was a number of changes that were occurring in October of 2005.

Then we jump ahead to the present and the FSA that just took place in September of '07, once again in response to illnesses with *E. coli* O157:H7, that were reported and clustered in the northeast, there was also a case in Florida, where that food safety assessment actually showed that there had been many, many changes to the programs, probably due to new management. They were trying a lot of different control programs, and a lot of those changes, the company was not actually making the necessary

verification activities for the new programs, weren't implementing the new programs very well, so the fact that they did not consistently execute those controls to make ensure that the source material were free of pathogens, actually was the underlying cause, and that goes back to the example I had just presented to you with the hazard analysis and how important that is when a company determines what food safety hazards are reasonably likely to occur.

In this particular case, there was a lack of understanding of the hazards associated with *E. coli* O157:H7 and the appropriate controls that the company had in place. They really did not reassess appropriately based on the information that the Agency presented in the Federal Register.

They also had a lack of ability to identify problems at the establishment and at the establishment level which played a part in that problem. There was a lack of support and sound decision associated with the hazard analysis. Basically the hazard not reasonably like to occur determination was not supported in the hazard

analysis. There was a lack of sufficient process controls in place and verification of the appropriate implementation. There was a failure of the purchase specification program that they had designed when receiving in particular imported product, but also a failure due to the COAs that they were receiving from other suppliers to verify that the slaughter plants that were supplying the establishment actually were functioning. So they really had designed a faulty purchase specification program and since that was the beginning of the process, the whole system basically failed.

So they also failed to properly identify the intended use of the product and this factor, the fact that they didn't really look at the intended use, also played into the food safety decision making that was faulty.

So all of that together, of course, resulted in the massive recall and problems at the particular establishment.

So in response to the OIG audit in December of 2007, the Agency set about looking at the risk-

based inspection system, and we have been working on developing the Public Health Risk-Based Inspection System which actually is vastly improved over what was previously thought of as risk-based inspection.

The system now would be able to improve inspectors' understanding of *E. coli* O157:H7 hazards and controls because the system is more closely linking activities to the regulatory foundation and citations to increase that understanding, so that when inspection personnel perform procedures, they actually understand the regulatory basis for performing that procedure, and what they're supposed to be looking at. The system also fosters inspector thinking in terms of the overall food safety system to provide a broader understanding of what those hazards are.

There will also be automated monitoring of the inspection result and built in alerts of anomalies including a lack of inspection activities. That's going to also assist. We're going to enhance the data collection and assessment to allow more timely reaction to emerging trends. If the system

had been in place, I'm sure that some of the problems at Topps would have been identified a lot sooner, and probably would have been stopped a lot sooner than it was rather than producing all the illnesses.

There will also be changes in the establishment's HACCP plan when the establishment makes changes because the enhanced profile will be kept up to date, their system will identify those and inspection personnel will also know about those changes that go into the system and the profile so that can be more easily monitored than it is today with our current PBIS system.

Additionally, we'll focus on the identification of vulnerabilities within the overall food safety system. As I pointed out, the problem at Topps was that their decisions were not supported, and they had a faulty design of the program. So the program did not work. They also had some execution problems in not verifying their program was actually working.

The new system will focus activities and include the control points as Carol indicated and

this should be addressed in prerequisite programs and sanitation SOPs in support of the hazard analysis. It's going to focus on verification questions to address the presence and appropriate implementation of process controls. Once again, we're looking at the capability of the process in terms of the whole system. So we're evolving. Once again, it's not something new. We're not doing something new. What we're doing is we're evolving where we should be and continuing on doing the procedures that we should be doing to make it more consistent and uniform. So this is going to help as far as consistency and uniformity.

Receiving has been identified as a potential vulnerable point as I indicated in my example, and we're going to focus on verification questions at that point including the use of purchase specifications programs. We had the system in place before, inspection personnel were known to look at those purchase specification programs and could have more easily identified potential issues with those programs.

And then also we're going to focus verification questions including some related to whether the produce was properly marked for the intended use. That also will bring more consistency in looking at how the establishment puts down and identifies what the intended use of that product is and also has decisions associated with the design of their program with the intended use in mind. We know that a lot of companies have not done that. In the case of Topps, they did not do that. So this will also help improve.

And then the profile will include the establishment's HACCP system that will allow review to ensure that the food safety hazards are identified and controlled.

So in summary, I just want to say that again, as Dr. Raymond indicated, this is a work in progress, and we certainly want to hear from you as we evolve into the new Public Health Risk-Based Inspection System. We think that the system that we're designing will improve the consistency at the in-plant level because it will be data driven,

science based and there will be a better understanding by inspection personnel of the systems approach. We will also ensure that OFO focuses the inspection resources at those establishments, producing those products identified by the expert elicitation as having the highest risk to public health, with the same goal and mission that we have today, and that is to protect the consumer that eats meat and poultry product. And as Carol indicated, the system is resource neutral. Thank you.

MR. TYNAN: Okay. Thank you, Dr. Arnold. Thank you, Dr. Dreyling.

I'll open it up for a couple of questions from the Committee here, and then Mrs. Foreman has a question, and then we'll go onto the next topic. And I think Dr. Bratcher had his tent card up first.

DR. BRATCHER: A couple of questions, Dr. Arnold, about Topps. What was the educational background for the inspector that was in that plant? Do you have any idea? And I assume that that was an IIC on a patrol assignment? Were there any plants added to that patrol assignment when we did the

method of assigned work? And, number two, what was the educational background and the workload measurement for the front line supervisor that was over that CSI and then what was the educational background for that front line supervisor which would have been -- in the District Office?

DR. ARNOLD: Well, I unfortunately, because I don't work for OFO any longer, I am not able to answer those questions because in the Policy Development Division, I develop policy. I don't ask the individuals about their education and background. That would certainly be for OFO to address and so I don't know the answer to your question.

MR. TYNAN: Let's see if we can't find that out so that when we get to the general discussion or at least at some point when the Subcommittees get together, that we have that information for you.

Mr. Covington, why don't we go to you next, and then we'll come right down the table.

MR. COVINGTON: Thank you for the presentations. Based on the presentations, there's going to be quite a bit of data collected, and as

with all data collected, it's about the interpretation of that data. How is FSIS going to ensure that the questions that are asked are comprehensive enough to understand that data and also be able to correlate that to regulatory noncompliance?

DR. DREYLING: I'll take that in two parts. First the question in terms of comprehensiveness, we are evaluating the questions and having FSIS experts and having reviews such as our NACMPI Committee looking at the questions to be sure that they are comprehensive. We are going to be then analyzing those questions through the Public Health Information System and we're developing a special component of that called predictive analytics which we'll be monitoring consistently and looking for patterns, and we have done analyses as we're going to get into the next presentation that looks at the results of our inspection activities and uses them to look at public health outcomes such as *Salmonella* results. So we are doing initial tests to look at relationships and to identify how we should identify correlations.

And we're also going to be examining what the proper thresholds should be. Should it be that you should get one NR and we prompt you to look at the vulnerable points or should it be several NRs or repetitive NRs, and what would that number of repetitive NRs be. So we are trying to carry out the needed analyses right now to address those points.

MR. TYNAN: So, Mr. Covington, I think it sounds as though some of the detail that you're looking for will come in the next presentation.

Mr. Stromberg?

DR. STROMBERG: Thank you, Robert. My question has to do more with the nuts and bolts of how this new system is going to operate, and I'd like to know when an inspector records a NR and enters it into the system, how long is it going to be before the for cause procedure is going to be generated?

DR. DREYLING: As soon as the NRs are entered in the system, as soon as -- the inspector has to update the computer. It will go into the system, and the system will then prompt the inspector that they will have to complete this for cause

procedure, and we will be determining a time window in which they need to complete that procedure, that for cause procedure, and we will determine that for each of the specific product categories, but I think it will be a very short time period because we want it to be a follow up to a problem that was observed in the establishment.

DR. STROMBERG: Thank you.

MR. TYNAN: Maybe we can go into a little bit more detail on that when we get to the full discussion. Dr. Harris?

DR. HARRIS: Thanks. Joe Harris. A question about the -- as you went through the case studies, it occurred to me that for years now it's been the Agency's contention publicly at least, and I think in practice as well, that the in-plant inspectors are not trained and not their responsibility to evaluate the adequacy of various programs and, in fact, there was a lot of justification behind creating the EIAO group and the four weeks of intensive training that they go through.

As I was listening to the presentation on the case studies, it sounded a lot like now that burden is going to be shifted to the in-plant inspectors to consider adequacy of programs, whether or not those programs are being appropriately designed and implemented, and my question is what is the Agency's plans for insuring that these inspectors are trained to make those kinds of determinations? It's a lot of investment in training those EIAOs for four weeks at a time. Is it going to be that level of training for all inspectors?

DR. ARNOLD: Well, if I gave that impression, I apologize. We are still going to have the EIAOs making the determinations associated with the design. What the in-plant IIC is going to be doing as I indicated is just answering a simple question, yes or no, and they're going to just be asking, they have a prerequisite program, we know that in the profile, and are they implementing it, yes or no. We're not going to actually be looking at the design of that program. We're going to be looking at are they actually implementing the design,

and now a lot of inspection personnel are not looking at that.

MR. TYNAN: Okay. I'm going to ask Mr. Smith, I think he had a comment, and maybe -- okay. We can come back to that again in the general discussion. Mr. Kowalcyk?

MR. KOWALCYK: Thank you. I have a couple of questions related to this process versus current process and some of the language in your presentation as well as the technical report that's in our materials.

You talk about on your second slide vulnerable points in aggregate. How should we interpret this new system with respect to things such as zero performance standards for fecal contamination in poultry slaughter for example? I -- a little bit reconciled that this language in the aggregate versus the zero performance standard. How is that impacted in this program?

DR. ARNOLD: Well, the difference is the one has to do with a CCP and this has to do with control points where, as I said, we're evolving into

more enhancement into the HACCP system and looking at the system as a whole. Right now our inspection looks at points, a point here, a point there, and we're not very good at connecting those dots. So this is actually going to help the inspector to look at the overall system by prompting them to look at specific control points that the company has identified are important, and so that's where the difference is. It's not that we're not going to still be doing HACCP and the procedures looking at critical control points and evaluating critical control points. We're just going to be taking more of a systemic approach and looking at the system and the capability of that process to actually produce a safe product.

MR. KOWALCYK: And another follow-up question, in the documentation of the documentation and technical plans both in the processing and poultry slaughter. There's a discussion about sufficient evidence that there's loss of control. I think it would be unfair to ask you for that definition now, but is the Agency doing its part in

due diligence in determining what would be identified as sufficient evidence? To me, it seems like there's a gray area there that would be open to interpretation and it seems like the way the system is designed, you want to avoid that, and I'd like to know a little bit more about what the Agency is doing at getting the definition that will be transparent to stakeholders and that info could be provided.

DR. ARNOLD: Well, the reason that the system is designed with multiple questions is that's how we get the aggregate. We're looking at multiple control points throughout the system. I know this is a shift from what we've been doing. We're going, like I said, back to more of a systems approach and looking at the entire process. So when the inspector is looking at those vulnerable points and identifies, no, they didn't do this at this vulnerable point and, no, they didn't do this at this vulnerable point and, no, they didn't do this at this vulnerable point, and we have multiple occurrences of that, that system is no longer in control and we have reason to be concerned about the system.

MR. KOWALCYK: Okay. Would --

MR. TYNAN: Michael, I don't mean to interrupt. Okay. It's got to be a quick question so we can get everybody through and get to the next topic.

MR. KOWALCYK: I think it's important to be said that I think it's important to look at the entire system and that there's a lot of merit behind that but there are, and even in your literature review, there are some critical points in the system that have greater impact on public health and, you know, in order to -- some results that are mixed.

Now if the Agency wants to take an approach that is aimed at improving public health, I would hope that the Agency is very clear with stakeholders as to what they would consider sufficient evidence. It can be one point in the system, but if that point is critical, that should outweigh maybe two or three other points if there's mixed evidence as to the efficacy of those interventions. And in the documents that I've seen, I haven't seen any clear distinction or any weighting that would be sensitive

to that public health impact, and I just want to be on the record that I recommend the Agency look into that.

MR. TYNAN: Thank you, Michael. Carol, did you want to make a comment?

DR. MACZKA: I do think that we have tried to identify those points that we consider most vulnerable, and not all the points are equally vulnerable. So based upon the scientific literature, we have identified the vulnerable points. And also about whether there's sufficient evidence, I think when we get to Dr. Travis presentation, I think the criteria that puts you into LOI 1, 2 and 3, I'd like to see what your reaction is to whether you would agree with that criteria because we think it is very transparent as to why you end up in one of those three categories.

MR. TYNAN: Okay. Dr. Negron?

DR. NEGRON-BRAVO: Yes, I would like to add just that HACCP has always been like a systematic approach, but I think the importance of the prerequisite program has never been precise enough in

the -- so I'm just asking is the Agency moving toward doing legislation or be more strict to the monitoring and the verification of those significant programs that now we are beginning to -- vulnerable points maybe throughout the system?

MR. TYNAN: Mr. Smith, do you want to respond to that?

MR. SMITH: Yes. We want to make clear that the actual HACCP rule put that into effect back in 1996, that the hazard analysis that we talked about here requires that all these decisions be documented. And what we're asking inspectors now to do is go back and see the evidence that these systems are in place to support this hazard analysis. So this is not new. It's focusing them on that as well as recordkeeping and as well as CCP.

MR. TYNAN: Does that help, Dr. Negron?

DR. NEGRON-BRAVO: Well, I know this is not new but it's not being done.

MR. TYNAN: Okay. I'm going to ask, Mrs. Foreman, can you hear us? Did you have a comment or a question at this point?

MS. TUCKER-FOREMAN: Well, not right now. Thank you.

MR. TYNAN: Okay.

MS. TUCKER-FOREMAN: Can you hear me okay now?

MR. TYNAN: Yes, excellent.

MS. TUCKER-FOREMAN: Okay. Thank you.

MR. TYNAN: Much improved. You called your provider in the interim?

MS. TUCKER-FOREMAN: Yes.

MR. TYNAN: Okay. Mr. Painter, I'm going to let you have the last word again.

MR. PAINTER: Yes. I'm going to start out with page 4, more specifically slide number 8. It talks about batter, breading, solution and things of that nature. I'm wondering -- my question is, does that mean the Agency's going to get back into the business of monitoring restricted ingredients such as the phosphates and -- and then I want to move onto the Topps situation, and although Topps, in my opinion, had some culpability in the situation, that resulted in the recall, in my opinion we're missing

the big picture here. The big picture here is the fecal contamination came from the plant, and we have these facilities that are running 300 something cattle per minute, and it seems as though there's been a lot of emphasis placed on education. And I want to be clear that we have a lot of people such as myself that are inspectors in the field that have achieved a higher level of education versus a sixth grade education. And it does not take a rocket scientist to see fecal material provided the line is not going at such a speed in which to do so.

MR. TYNAN: Okay. Thank you, Stan.

MR. PAINTER: What about the question regarding the -- and the restricted ingredients?

MR. TYNAN: Okay. I apologize. In your discussion, I may have forgotten what the question was.

(Laughter.)

MR. PAINTER: I'm sorry. I didn't mean to be so long-winded.

MR. SMITH: Well, we can -- again the HACCP rule requires that a hazard analysis be done on each

step of the process and that's where that would be analyzed and that then is getting into how the plant either makes that a critical control point or says it's not a hazard due to a prerequisite or a control program, and that's what we're saying, then we would look at in performing the inspection. So that is covered.

MR. TYNAN: We can have further discussions, Stan, if you have other questions when we get into the full group.

We're at that point, we've talked a little bit about the in-plant inspection activities and now what we'd like to do is talk about a slightly different aspect of the concept which is across plants, and I have Dr. Curtis Travis. He's a consultant with Science Applications International Corporation. And he has a two-part presentation. We broke it in parts to allow a little bit of discussion. So the first part will be the overall concept and then he has a second part that will talk a little bit about attribution. So we're going to take the first part first, and take a little bit of

break for questions and then we'll come back to do the attribution. Dr. Travis.

DR. TRAVIS: Thank you very much. I'm going to talk about the across establishment ranking concept for processing and slaughter.

The goals of the ranking algorithm are to focus FSIS resources to ensure food safety systems are working efficiently. There's sort of two components to it. One's the across establishment algorithm which is to focus on establishments with evidence of a lack of process control, and then the within establishments. The component of the ranking algorithm is to focus on the most vulnerable food safety system areas. And one of the goals was to remain resource neutral.

This is a large overview. The analogy here is what the sort of triage system used in critical medical situations where you're separating patients into those that are about to die, need some medical attention or fine. We're trying to triage establishments into three levels of inspection. Those that would receive routine levels of

inspection, those that would get more attention but not critical attention, and those that are going to receive in-depth inspection. That's the general concept is triage plants and that triage would determine the level of inspection.

The secondary concept that we're going to discuss is what criteria do you use for triaging. That's really the meat of the triage system.

Risk has two components, magnitude and hazard. And risk formally is defined as the product of magnitude times hazard. Magnitude is like the number of illnesses that might occur and hazard is probability of illness.

Both components help FSIS to better focus its inspection activities. We're using attribution as the measure of magnitude which the second part of my talk is about attribution which is sort of which percentage of illness comes from different food products. It helps us focus on the pathogen product pairs that most contribute to human disease. And the hazard component which is the effectiveness of process control, that let's you focus on

establishments with less than optimal food safety process control systems.

This is a picture that shows those two components. It says that establishment public health risk ranking is basically a function of two different components. One is the magnitude of the public health impact which we're going to estimate as the establishment volume divided by the national volume. That's just a fraction of volume for a plant, what fraction of the total national volume for a product that that plant is producing times the public health attribution. And this gives you an indication of the fraction of human disease an establishment might cause if a contamination event were to occur.

The hazard component is we're evaluating using indicators of process control and there are a couple of different kinds of indicators. One is measurements over time, like verification testing or health based NRs, and the other is episodic measures like FSAs or recalls or enforcements. Those only occur once in a while and maybe randomly. And they're indications of how well the establishment is

maintaining process control.

Okay. So we want to sort the establishments into three levels of inspection. The LOI 3 is going to be based on specific criteria. LOI 1 is based on specific criteria that we're going to define here in a second. And then the remaining ones are going to be in LOI 2. You can define criteria for that also but basically that's the easy one. Once you get the other two, the high and the low, you've got the ones in the middle.

Now in terms of the level of inspection that will be focused towards these different groups. And LOI 1 is the one that will receive routine inspection. So you're going to maintain routine in-plant inspection and you'll have these focused verification activities prompted by in plant results to identify and prevent possible problems. These are the for cause prompts.

In LOI 2, you're going to focus verification activities at the vulnerable points to identify whether there is a food safety system problem. You would be using both directed procedures

and for cause prompts, and I'll talk about these two in the next slide.

In LOI 3, this is where we have focused in plant verification activities. They will be getting both directed procedures and for cause prompts, and the idea here is to deploy the highly trained resources for in depth assessments and verification. This is where you would get your immediate -- well, fairly rapid food safety assessments at the facility.

The food safety assessment component here is fairly important because the OIG and FSIS both recognize that food safety assessments are one of the best tools we have for identifying whether plants have effective food safety control systems in place. And so we would want to do food safety assessments at the LOI 3 plants and also some of the LOI 2 plants.

Okay. This is the different procedures. You've seen this graphic several times. It basically says we have for cause procedures which would be when you get a NR, then the inspector will be prompted to go upstream and look at the vulnerable points.

And the other way is directed procedures

which is in the LOI 2 and LOI 3 establishments. Here inspectors can be prompted to look at vulnerable points even though there wasn't any prompt, a NR may not have occurred but they'll still be on a random basis told to look at various vulnerable points.

This is a slide that Carol also showed. It's just again the conceptual approach to the ranking. We start with all of the establishments. We're going to separate them into three levels of inspection based on process control effectiveness.

Then within LOI 2, we're going to rank them based on public health impact. The reason that we don't rank the other two categories with regard to public health impact is that LOI 3 are all going to get focused attention. So there isn't any need to rank them. And LOI 1 is receiving your routine inspection activities. So again, there isn't a need to rank it. So we're only ranking the ones in the middle with respect to public health impact.

Now we're going to look at the criteria that are used. One of the things that I want to emphasize is that these criteria aren't carved in

stone. FSIS is looking for your input on them, suggestions as to whether some other ones may be added or some of these might be deleted. This is sort of an intuitive question. I mean you're asking yourself, what kind of criteria would I want to use to judge if a system needs more inspection, or to judge if their food safety control systems aren't functioning optimally.

So these are the criteria that we have. One is a positive *E. coli* O157 verification test in the last month. One other question we want input on is what time period should we be using. Should we go back to the last month, last two months, last years? What kind of time period should we be considering? The reasoning here was that you don't want to go back too far because a plant may have had a condition in the past, a year ago, corrected everything and be working fine now and they don't want to be penalized because of that right now. So you don't want too long of a time window.

Number two, a positive *Lm, Salmonella* or *E. coli* in RTE products in the past month.

Establishment in *Salmonella* Category III, those are the ones with the highest percent positive *Salmonella* on the *Salmonella* verification testing. An establishment that is linked to a disease outbreak. An establishment that has sustained structural damage due to a natural disaster.

An establishment that's in the STEPS database more than once in the past 120 days, the shipment of a specified risk material, an enforcement action or adulterated or misbranded product shipped. This includes recalls. The highest percentile of health-related NRs, for instance, SRMs, insanitary dressing, zero tolerance, residue, over some time period to be determined. Again, this is over like a month, over two months, over a week.

The use of NRs justified through predictive analysis, that's going to be my next slide. I'll talk about that. And a repetitive *Salmonella* serotype of human health concern or PFGE match. I point out that this criteria is not currently being applied. FSIS is collecting data for this particular criteria through part of the *Salmonella* Initiative

Program.

FSIS employed Carnegie Mellon University to do a variety of statistical analyses of the data. That whole suite of analyses was called predictive analysis. They want to use the FSIS data. The want to mine it and figure out which subsets of it could be used to predict the occurrence of events before they occur.

So one of the questions that they asked was if a NR occurs, what is the increased probability of a positive *Salmonella* in the next two weeks? Or is there any?

This graph on the right shows their analysis and there's three different graphs there. The solid one at the bottom was using all NRs. The middle one was, yeah, that one, was NRs that were based on the industry coalition in response to the last RBI, proposed a set of NRs that they considered related to public health. And then there was a FSIS proposed list which we call Type 3 NRs which, out front, there was a list of all of the NRs. It was on a sheet, and the FSIS group had split them into four

groups that they weighted as 0 weight, 1, 2 and 3. Three was the highest. It was clearly related to public health. That's the group that we're using, and this is the group that CMU did their analysis on.

So they looked at these three different groups, the public health related NRs that FSIS has proposed, the public health related NRs that the industry coalition had proposed and all NRs. And asked the question, if a NR occurs, is there an increased probability that *Salmonella* will occur in the next two weeks?

And the graph shows that this is your looking back window, at the bottom down here. So it says 7 days, 14 days, that's when you're looking for your NRs. So you're saying if a NR occurs in 7 days, then I'm going to look forward in the next 2 weeks and predict if there's an increased probability of *Salmonella.* And you can see that all three of these measures of NRs predicted a higher probability of the occurrence of *Salmonella* for a plant that had had one of these NRs versus a plant that didn't. And if it was one of the FSIS NRs, it was probably about 3

times higher. The industry coalition NRs had a probability of about 2.3 times higher. But even using all NRs, the probability was about 1.9 times higher.

The differences between them are statistically significant as you can see because their error bars don't overlap and they're all statistically greater than one which would be an equal chance of having the *Salmonella* or not having *Salmonella.*

Now as your window goes out, I mean you take a longer window on the NRs, moving backwards like 14 days, 28 days, 56 days, the probability has come down, but they all stay above 1, meaning that NRs are a predictor of the occurrence of *Salmonella* in the next two weeks.

So this is one of our justifications for including NRs.

Okay. Now we move to LOI 1 which is the routine level of inspection. Here we are requiring that establishments must satisfy all of these criteria. So we want it to be particularly

efficient. It has to satisfy all of these criteria to get into LOI 1.

Back when we were doing LOI 3, which was the focused inspection, all we required was that one of those things occurred. If one of those things occurred, it went up to the top. Here we want them all to occur to get into the bottom.

So one is that no positive *E. coli* O157 in the past 120 days or until the establishment is determined *E. coli* free from follow up sampling and 120 days is based on the approximate time it would require to do the 16 follow up *E. coli* samples.

No positive *Listeria, Salmonella* or *E. coli* O157 in RTE products in the past 120 days.

No enforcement action in the past four month or adulterated or misbranded products in commerce in the past four months and again this includes recalls.

Establishment is not linked to a disease outbreak in the six months. A lower percentile of *Salmonella* percent positives on the most recent sample test, unannounced sampling or other *Salmonella*

testing programs.

We haven't set what percentile we might use. We need some input on that. But in some preliminary runs, we were using 70 percentile. So as long as you were in the lower 70 percentile, you could get into a routine level of inspection.

And the next one is lower percentile of public health NR rates over a period of time to be determined, same thing, over a month. That's the period of time that we're using now. And again, the use of NRs justified through the predictive analysis that Carnegie Mellon University performed.

A lower percentile on the most recent FSA score. This criteria isn't currently being used but it will be used as more FSAs are performed. FSIS is developing a scoring system for these so that you will have a numerical score assigned to each FSA and we're looking to say that you need to be in the lower percentile on this score in order to be in the routine level of inspection.

A lower percentile of scores on focused in-plant verification questions, the vulnerable points.

Now this is part of the second part of the algorithm of looking at in-plant inspections and focusing on the vulnerable points and having inspectors ask questions and get answers. Those will be scored and based on the scores for those, that will also be feeding back into the first part of the algorithm which is across the plant prioritization. So we'll get real time results from inspectors looking at the establishment and asking questions about food safety controls at vulnerable points and those will be fed back into the system to help with prioritization. That's not currently being done but it will be done.

And the lower percentile of *Salmonella* serotypes of human health concern and PFGE matches. This comes about because not all *Salmonella* cause disease in an equally efficient manner. The different serotypes cause more disease and also different serotypes occur more often with certain food products. So we want to actually take that into account and FSIS is now collecting serotype data on *Salmonella* in the products that FSIS inspects, and that will be fed back into the system also.

Now we have the middle which is focused inspection, LOI 2, which is establishments that aren't in either 1 or 3. You can stop right there if you wanted to and say, okay, it's everything that we haven't defined, but we'll talk about what some of those criteria are.

One is an *E. coli* positive within the last 120 days or still undergoing follow-up sampling, for which a FSA has been completed. Another is a positive *Listeria, Salmonella* or *E. coli* O157 sample within the last four months for which a FSA has been completed. The reason that last tag line is on there, for which a FSA has been completed, because if it hadn't been completed, it would be up in Category 3. We don't want the establishments to stay in Category 3. So once they get into Category 3, you're going to have a FSA and they're going to have to correct whatever problems they find. I mean either they'll be fined in which case they're going to move down to either 1 or 2, or they will correct the problems and move down to 1 or 2. So in order to get into level 2, the FSA has to have been completed.

An enforcement action or adulterated or misbranded product shipped, this captures recalls, in the past four months, for which a FSA has been completed and corrective actions have been verified. That goes with the top ones, too. Not only does the FSA have to be completed, but the corrective actions have to be verified.

Based on the past history of *Salmonella* testing, they're above the lower percentile cut point for LOI 1 for percent positives on the most recent sample set, unannounced sampling or other *Salmonella* testing programs. Or NR rates similar, they're above the LOI 1 cut point and below the cut point for the NR to get into LOI 3. It's in between those two.

In the STEPS database more than once in the past 120 days, for which a FSA has been completed. Above the lower percentile cut point on the most recent FSA score; above the lower percentile cut point for LOI 1 of scores on focused in-plant verification questions, the vulnerable points; above the lower percentile cut point for *Salmonella* serotypes and an establishment's been confirmed to be

the cause of an outbreak in the past six months, for which a FSA has been completed.

Okay. That was a long list of criteria for LOI 2 but it's really just a simple concept. LOI 3 has a fairly short list of criteria to get into that. LOI 1 which is the routine level of inspection also has some fairly clear cut criteria to get into it, and everything else goes into LOI 2.

Now within LOI 2, FSIS has proposed to rank the establishments based on a measure of public health impact, and this is going to explain that measure. Basically it's the fractional volume times attribution for the product and pathogen that the establishment produces. The fractional volume is simply the volume that the plant is producing divided by the total volume of that product being produced. And it's obviously product specific. So, if you were looking at broilers, you'd want to know what's the volume of broilers that this facility produces and then you would divide it by the total volume of broilers being produced, and you'd get that this facility is producing one percent of broilers. That

would be your fractional volume.

Then you have an attribution for a pathogen product class, like the ground beef consumption causes 34 percent of all *E. coli* O157 illness. We're going to talk about that next, how we come up with attribution numbers.

The public health impact is then the fractional volume which is the Vi divided by summation Vi. That's just the fractional volume of production for the plant times the attribution.

If an establishment produces more than one product with the same pathogen of concern, we select the maximum potential public health impact.

Then we are proposing to sort the establishments into one of four pathogen categories, *Salmonella, Listeria, E. coli* and *Campylobacter,* and a fifth category for plants that we don't have pathogen results for.

Now that's already going to be done earlier on because when we were looking at the beginning part of this ranking algorithm, we were taking fractional volume times attribution, attributions for a specific

pathogen and product. So in order to perform that part, we've got them separated into categories in terms of *Salmonella, Listeria, E. coli* or *Campylobacter.*

And then we're going to split these into a lower and upper 50 percentile. So for *Salmonella,* they would be split into a lower 50 percentile and upper 50 percentile, et cetera.

And then depending on FSIS priorities, for instance performance standards or seasonality or focused on a particular product, these could be amended or the focus changed. This just allows you to have a slightly finer focus in your prioritization for these middle categories. It can also be used to help focus which establishments should be receiving food safety assessments.

In summary, the public health risk-based algorithm is designed to focus inspection on establishments most needing attention, focus inspection on the most vulnerable food safety system areas, and verify that food safety systems are working optimally.

The approach has multiple advantages. Carol mentioned these earlier. One is transparency. You don't have a bunch of formulas that you have to compute. You don't have a bunch of numbers you have to add up, things you multiply, whatever. You just have these criteria. You can say, okay, in order to get focused inspection, what kinds of things do I think should be considered, like if they've had a positive *E. coli.* So it's fairly transparent as to what gets you into one category or another. It focuses on plants with evidence of lack of process control. These are plants like they've had an outbreak associated with them. It indicates a lack of process control. So, if they have higher *Salmonella* levels, it indicates that they do not have optimal process control.

It focuses on plants with high pathogen levels. So, if you get high pathogen levels, relative to other plants, producing the same product, it's a fair comparison. Then you are going to get more focused inspection attention.

All plants with health related problems,

recalls, outbreaks, enforcement actions, are ranked high. That seems like that that would be what you would want to do. If plants are having problems, you'd be wanting to do a food safety assessment on them. You'd be wanting to make more focused inspection attention.

The categorization is independent of production volume, that is separating the plants into the three levels of inspection doesn't depend on production volume. It only depends on these various criteria that we put forth.

And the system is compatible with the FSIS risk-based sampling programs.

The next steps, we want to apply the algorithm to existing FSIS data. We've already done that for poultry slaughter. I'm going to talk about that tomorrow. We're in the process of doing it for multiple other categories. We've actually finished ground beef but haven't written it up yet. We're in the process of writing that up, and we're doing ground chicken, ground turkey. We're going to do all of it. So that's where we are now, gathering that

data and doing the analysis.

We want to have external reviews of this algorithm. That also is underway. All of this material has been sent out to external reviewers and they're reviewing it. We're, of course, getting your input and public input. I emphasize that this algorithm is only a proposal. We'd like input on the various criteria, whether anything's been missed on the time periods that we're considering and on the cut points that we're considering.

And we want to also examine the relationship to pathogen specific sampling programs. I said that this algorithm was compatible with those systems. It is but we want to check in detail what they would predict should be at higher risk sampling versus what we would predict using this algorithm and see that there aren't any holes in this. Thank you.

MR. TYNAN: Okay. We're going to take a couple -- just a couple of questions. Dr. Travis has another portion that he wants to address regarding the attribution but before we go onto that, we'll take a couple of questions from the committee and

from Mrs. Foreman. Mrs. Foreman, can you hear us? Did you have a question that you might want to pose at this time? We'll start with you.

(No response.)

MR. TYNAN: Okay. We'll come back to Mrs. Foreman. Mr. Elfering, did you have a question?

MR. ELFERING: Yes. Kevin Elfering. I actually have a couple of questions. One is again related to what are true public health issues, and the SRM removal, you know, if it's a high, high priority, I can still see doing the work but maybe it shouldn't weigh so heavily on this particular issue actually going from a LOI 1 or 2 and LOI 3 plant.

The other thing is, what is a public health significance is some issues with non-Shiga toxin-producing *E. coli* which have been found to contribute to HUS. Is the Agency going to be looking at non-Shiga toxin *E. colis* as well as just O157:H7?

The other question is on recalls, non-public health recalls, will that have any impact on categorization and it doesn't appear, or at least I couldn't see it in here, the LOI 3 plants, there's no

discussion on recalls that I could see at all, and maybe I just missed it but the LOI 1, if it's a non-public health issued recall, would they have changed categories?

And then I have one final question and I'll let Dr. Raymond think about this one. Does this fit your vision when you rolled this out to us initially, does this fit your vision for risk-based inspection in a LOI 1 plant and you're still maintaining routine inspections or is there going to be less inspection in those particular facilities?

DR. RAYMOND: We'll go with the last question first. There won't be less inspection at the LOI 1s. At this point in time, the minimum level of inspection we currently do would be maintained at all plants. One of the reasons we can say this is resource neutral is because the Level 3 plants will be receiving those resources that we currently have available, the FSAs, et cetera, the in-depth verification testing, those things are done, they'll just be focused more on those plants.

I'd like the comment on a couple of other

things if I could. Kevin said this twice now about public health based risk inspection and why do SRMs keep popping up. I mean, Kevin, I couldn't agree with you more. The time and money and effort and energy that we've spent on SRM removals since the cow went down in the State of Washington, if we had spent that much time and energy on *E. coli,* I don't think we would have had the problem we had this summer.

Unfortunately, that is an issue that we spent a lot of time on, and I will defend using SRMs as one of the categories for popping a plant into a Level 3, because if there should be SRMs, they really truly are showing a total disregard for what the business is all about. So they may be neglectful in other areas as well. It's a very glaring error of commission.

So I think we should leave it in there because it indicates types of practice, admitting that it's not a public health risk problem, but the magnitude of *Salmonella* or *E. coli* and then the issue you raised about the O157:H7 STECs, we haven't made that decision but as yet, we certainly welcome the

input of this Committee or anybody else. We have had a day meeting on that issue. We're taking a look at whether or not those bugs should be declared adulterants and zero tolerance for them as we did for O157:H7, just so which ones on the STECs should we declare. They're like *Salmonella,* they have varying levels as we all know that have a big impact on human health, but that is an issue that does need to be addressed. Thank you for bringing that up in this discussion.

MR. ELFERING: I guess I'd just like to follow up on one thing with the SRMs again, and the reason I bring it up is I really like to try to focus and maybe I've been a HACCP geek for too long, and I look at hazards that are reasonably likely to occur but in the same breath, I believe that live ammunition, stunting of livestock, is still being utilized in some plants and there has been studies showing that there's been brain emboli found in cardiac heart muscle in those animals that have been stunned with firearms and until that is prohibited, then you're still not removing SRMs.

DR. TRAVIS: With regard to recalls, it actually appears on slide 11, and it's under the adulterated or misbranded products. It says it captures recalls. So recalls is definitely a criteria to get into LOI 3.

MR. TYNAN: HACCP geek. Is that a scientific term, Kevin?

MR. ELFERING: Class 1.

MR. TYNAN: Okay.

MS. TUCKER-FOREMAN: This is Carol. I do have a question if it's appropriate.

MR. TYNAN: Please go ahead.

MS. TUCKER-FOREMAN: Okay. I have first of all Carnegie Mellon report, Dr. Travis, is that available? I don't believe that I've ever seen that.

DR. TRAVIS: Yes, it's an appendix.

MS. TUCKER-FOREMAN: Which appendix is it please?

DR. TRAVIS: E.

MR. TYNAN: E as in echo.

MS. TUCKER-FOREMAN: Thank you. I'm a little surprised that you're asking us to come up

with an appropriate period of time for some of these things. I would think that you have data relating to an actual public health problem, for example, -- criteria. I don't see any evidence in the criteria other than that there's been a link to an outbreak that any of these specific provisions have any relevant -- can be directly connected to a human health illness, a human illness. How does that work? The lower percentage of *Salmonella* percentage positives can be assumed but are there any data that show that, in fact, a plant that has a higher level of *Salmonella* positives has had more public health illnesses, human illnesses traced back to that plant?

DR. TRAVIS: Well, I'm not aware of it being like that but what we're trying to do here is to tie this to food safety control systems, and these are indicators of effective food safety process control. So a higher level of *Salmonella* is definitely an indicator of not optimal food safety process control systems.

MS. TUCKER-FOREMAN: Okay.

MS. TUCKER-FOREMAN: And there is a leap going from

the fact that if an establishment doesn't have optimal food safety process control systems, that they would cause a higher number of health impacts but I think that that's a generally accepted assumption that good process control lowers public health impacts.

MS. TUCKER-FOREMAN: Okay. I agree with you but I wanted to make the point that these are assumptions, that we don't really have any scientific hard numbers back up -- about process control just before we get to the point where we all bow down and worship at the alter process control, I think some of the limitations and process control or acknowledge limitation about process control should be mentioned.

I have a couple of follow up please. The second one, my second question is about triage. You started out here talking about the system of triage and I think that generally appropriate, but the triage system at some point, the doctor walks in and says, that patient can't be saved. We are not going to invest scarce resources in taking care of that particular human being. They're DOA.

In fact, in this system, it's the DOA patient that gets the most resources. It seems completely contrary to the system of triage as I know it. Is there any point where FSIS decides that plant can't fix itself and we can't help it fix itself or it requires far too many of our public resources to fix that plant. I don't see that mentioned anywhere.

MR. TYNAN: Mrs. Foreman, I think there's a couple of responses. Dr. Raymond, did you?

DR. RAYMOND: Yeah. Carol, having been there on that side of the fence as a practicing physician, I do know what you're referring to but the plants for the great most part we'll see go to Level 3 and uses these greater resources, they're not DOA. They're still producing meat and poultry products. They went out there for consumption, and so therefore the resources will be spent to help them become better plants to move to a Level 2 than to a Level 1 plant so that the food products are safer. I would consider this rehabilitation and physical therapy rather than pulling the plug.

MS. TUCKER-FOREMAN: Well, I guess my

question to that is at what point do you determine that, in fact, a plant doesn't deserve, and we've been over this before, doesn't deserve this continued investment of scarce public resources? Where is it written that a plant that just doesn't make it gets to stay in business?

DR. RAYMOND: And, of course, that's when we do the food safety assessment to make that determination. If that determination has been made, then we would pull inspection services which effectively suspends that plant from any production, and if they wanted to come back up, they would have to present a plant to us and we would watch them very closely. But at some point in time, some of those plants just simply close the doors as did Topps and Ranchers this year.

MS. TUCKER-FOREMAN: Yeah. Okay. And I still continue to find it a very basic flaw that we continue to invest scarce public resources in keeping marginal plants in business and I applaud your second year of proposing that there be user fees for plants that require more than the average investment of

those resources.

My third question is that all of these standards are based on mysterious *Salmonella* or *E. coli* O157:H7. *Campylobacter* is the single most common cause of acute bacterial gastroenteritis among humans and yet it is not used anywhere in FSIS' proposal as a standard by which to judge a plant. It is most commonly associated with undercooked or raw poultry. We're dealing with a poultry slaughter proposal and there is no basis for making these -- *Campylobacter* doesn't figure in making judgments about the level of inspection that plants get. Can you tell me where --

MR. TYNAN: Dr. Maczka, do you have a response to that?

DR. MACZKA: Yes. I do think that Dr. Travis did mention that *Campylobacter* will be used in LOI 2 and, too, as we collect more information on *Campylobacter,* it will be used within all of the levels, and I think if Dr. Engeljohn was here, he would jump up and down saying that's so.

MR. TYNAN: Okay. Mrs. Foreman, if you

don't object, could you hold your next series of questions until we have the open discussion. I have -- I'm going to ask Dr. Dickson maybe to finish up and Mr. Kowalcyk to maybe hold his question until we get to the general comments.

MS. TUCKER-FOREMAN: That was the end of my questions. Thank you.

MR. TYNAN: Okay. Thank you.

MR. DICKSON: Thank you. Just a quick comment here. On your LOI 1 criteria, relating it to establishments linked to disease outbreaks, I would suggest that for consideration that you perhaps look at longer term for the establishments, such as a hypothetical establishment that may have been linked to say three foodborne disease outbreaks in the last five years. That might suggest that there is something with that particular establishment that is not necessarily routinely under control. That was the only comment I really had on LOI 1.

MR. TYNAN: Okay. Thank you. And thank you, Mr. Kowalcyk, for your holding your question.

I'm going to ask Dr. Travis to maybe get

into the attribution and perhaps we're a little bit behind schedule. So, if you could address that topic for us.

DR. TRAVIS: We can do this fairly rapidly. Let's start on the next slide.

Attribution, the definition, a pathogen-specific percent contribution of specific food items to human disease. Examples, 63 percent of *Listeria* illnesses are attributable to RTE products or 34 percent of *E. coli* illnesses are attributable to ground beef. Okay. That's attribution.

The approaches to attribution, when we say approaches, what do we mean? What we're trying to estimate attribution? If we had exact numbers for attribution, we wouldn't have to go through all of this effort of gathering data and estimating it. We don't have exact numbers and you should know that the numbers change every year. So when you make an estimate, you're just making an estimate in time. The next year they might be slightly different. But they're not changing hugely from year to year. They don't gyrate all over the place. They're trends, you

know, the levels of a certain pathogen in produce may be increasing over time but they don't jump to 100 percent and then down to 0 percent and back and forth. They tend to change within ranges. So we're trying to estimate something that's changing over time, and we have limited data for estimating it.

So here are the approaches for estimating attribution. One is risk assessments. So you can do a risk assessment to estimate what fraction of human illness comes from *Salmonella* in a product. That's done quite often. I mean there are quite a few risk assessments that try to do attribution. I mean that's generally not the primary their primary aim, but the secondary product of the risk assessment would be an attribution estimate.

The difficulty with using those is that they generally focus on a single product or process. So they might be doing chicken broilers or they might be doing ground beef, but we really need estimates for all of the FSIS inspected products. And in addition to that, we need estimates for the FDA inspected products if we're going to estimate the

attribution across all food items.

So risk assessments are good in that they're a focused attention on a particular food item generally or a particular process, but they're limited in that they usually only focus on a single product.

Expert elicitation is another method that's been widely used in estimating attribution. A criticism of it is that it's based on perception of experts and is not based on verifiable data, but various experts and advisory committees have said that it's often the best source of guidance when other data are sparse. Now that sentence makes sense. If you don't have any other way of estimating it, you could use an expert opinion.

Disease outbreak data is another source for estimating attribution. It's positive is it's real illness data. It's negative is that it doesn't include sporadic illnesses, and sporadic illnesses represent the majority of illness cases.

Serotypes, particularly for *Salmonella* is the method that's been proposed for doing

attribution, and it actually has been implemented in several countries. Its drawback is that it's not well established yet for use in attribution but FSIS is working with CDC and FDA in developing a serotype approach for *Salmonella.* That activity isn't complete yet, but when it is, we possibly will be able to incorporate that.

So now I'm going to go over the data that we used to come up with our attribution estimates. First is the expert elicitations. We're looking at two different expert elicitations, the FSIS expert elicitation which was 17 experts equally divided among the public health community, industry and academic institutions. Carol tells me it was 12 experts. Her first point was that 17 doesn't divide equally into these. It seems to me we caught this error once before and it crept back in. It was 12. They started with 17 but they paired it down to 12 so that they could equally divide them and have equal representation in these various areas.

Resources for the Future also did an expert elicitation that was completely independent of the

FSIS expert elicitation, had different experts and was performed at a different period of time, though both of them were published in 2007. They used 42 food safety experts and one of the positives about it is that it included both FDA and FSIS food products.

Okay. The next slide, this is just to give you an idea of what FSIS expert elicitation looked like. It's hard to read all of that because it's a bunch of numbers up there but basically there were 25 food types, if you count commercially sterile as one of the food types, and they estimated this is percent of disease that came from each one of these food types. So they're estimating that for *Salmonella* 8.9 percent came from raw ground chicken.

Okay. Next. This is the RFF expert elicitation. The first thing you notice is they didn't have as many categories and that they were also including FDA categories like seafood, produce, breads, dairy, et cetera. So it has its strengths and weaknesses. It doesn't get down as specific as the FSIS expert elicitation on various food categories of interest as FSIS but it also cuts

across broader categories. Okay.

This compares the two expert elicitations. If we collapse the FSIS expert elicitation back into these major categories. So how do you do that. Like for instance, meat. Well, you just look at the 25 food categories that FSIS ranked or told you the attribution for, and then you figure out which of those were meat products and then you sum up the percent attribution they had and so then you get a percent attribution for meat, for Salmonella and poultry, et cetera. And the other one is just straight from the FSIS expert elicitation, and you can see that they agree fairly well. Actually, when I first did this, it was surprising, the agreement between these two different independent expert elicitations, that they would agree this well. Okay.

A third database is the outbreak database. We used the database from the Center for Science in the Public Interest. It's a database that covers the years 1990 to 2004. There's now a 2005 component of it out that we haven't analyzed yet, but we're in the process of doing that. It covers 5,000 outbreaks.

It includes CDC outbreak data, and it has additional data from state health departments, peer-reviewed medical journals and verified medical reports.

And this is what their list looks like. They also have both the FSIS products in broad categories, just like Resources for the Future, and they have the food categories that FDA also inspects. Okay.

This is a comparison of all three studies. Again, there's very good correspondence between the three studies, and what I believe that this kind of a study shows is that one, there was questions about the FSIS expert elicitation in that these were only experts, how do you know this data is any good? Well, now you have the Resources for the Future expert elicitation that produced almost identical answers, and when you look at the outbreak data, it's producing almost identical answers. So that is sort of a verification of the FSIS expert elicitation.

The other way around, you say, well, there's some questions about the Center for Science in the Public Interest database, it's outbreak data

may not be everything, but now these two expert elicitations rank up pretty well with the outbreak data.

One of the things that I did over the weekend, since there's been questions about this CDC data versus the Center for Science in the Public Interest database is I went back and looked at the CDC data for the same years, that is 1990 to 2004, and looked at these same categories as the Center for Science in the Public Interest and again the expert elicitations compare fairly well.

That was a preliminary analysis. We're going to do a detailed analysis in which I transferred all of the data from CDC into a spreadsheet so that I can make sure that I'm classifying every food item into the proper category. It's not all that easy to do these kinds of classifications as you start, like if you were doing lemon meringue pie, do you put it in bakery goods, do you put it in eggs or do you put it in multiple ingredient products. So you want to be consistent in however you do it when you're comparing the CDC data

with the Center for Science in the Public Interest, but we are going to do that analysis and it will be available. But the preliminary analysis shows very good agreement between CDC data and Center for Science in the Public Interest outbreak data.

Okay. Now this last piece is just an application of attribution data to develop performance objectives. It's fairly straightforward. First off, you start with the CDC 2010 healthy people objectives. They're listed in this box down there. These are cases per 100,000, that is illnesses per 100,000. Well, it's actually positive cases per 100,000, that is verified cases of like for instance, *Salmonella.* Okay. The bottom part, the one for *Listeria* 2010 says .24 cases per 100,000 but by executive order, .25 was to be met by FSIS by 2005.

Okay. Here's the outline of the approach of developing a performance objective for FSIS. You simply take the CDC 2010 public health goal and multiply it by the fraction of illnesses attributable to that FSIS product category. You multiply it by the attribution.

Here's an example. The health-based performance objectives for *Salmonella* on broilers is 6.8 cases per 100,000. If you use the attribution number of 10 percent attributable to broilers, then you get a health-based performance objective for FSIS of *Salmonella* on broilers of 6.8 cases per 100,000.

The next one is for *E. coli*. The CDC objective was 1 case per 100,000, multiply it by the attribution of 34 percent attributable to ground beef, you get .34 cases per 100,000.

And finally, *Listeria* in deli meats, the CDC goal was .24 cases per 100,000, multiply it by the attribution estimate of 57 percent attributable to deli meats, we get .14 cases per 100,000.

This is the conclusion on attribution. The best estimates for attribution come from a combined approach of trying to use all of the available data. We've attempted to do that. The best available data sets right now are the two expert elicitations and the Center for Science in the Public Interest outbreak database. We're going to include the CDC database. So we're doing that analysis right now.

And then we will have what I believe to be the best available data for estimating attribution.

All of the available data appears to produce very similar estimates of attribution. As you can see in the one slide we had to compare, they're very similar.

And, we can use attribution to link FSIS performance objectives with the CDC public health goals. Thank you.

MR. TYNAN: At this point, why don't we take just a couple of clarifying questions regarding attribution if there are any from the Committee. If there are not some to clarify this particular presentation, then what I'd like to do is open it up for discussion of all the presentations this morning regarding public health risk-based inspection in processing and other slaughter activities. Mr. Kowalcyk.

MR. KOWALCYK: Thank you. Dr. Travis, in your work on this portion of the project, what would your recommendation be to FSIS for reconciling the fact that the data in the CSPI is only looking at

outbreak data as is CDC and even in the technical appendix because, you know, a small fraction of total foodborne disease is caused by outbreaks and in here it says that the remainder of 5 to 15 percent and then based on your analysis in the last few slides, those numbers don't necessarily seem to really show the whole picture? What would you recommendation be to the Agency as well as this Committee as to what we should acknowledge with respect to reconciling the fact that we're not looking at sporadic illnesses?

DR. TRAVIS: Well, I would say that you can only use the data that's available and the data we have available is the outbreak data. CDC has done some case control studies of some sporadic illness and I've looked at all of their studies that are on their website, but in general, they aren't usually that helpful. If they're looking at *Salmonella* illnesses, they'll trace it down to a couple of products but not the kinds of breakdowns that we need across all products. I mean to do attribution, you really need a breakdown across both USDA products and FDA products if you're going to get the percent

contribution to total disease.

And so the case control studies that CDC has done haven't been that useful, and I mean it's not a fault with their study, it's just very difficult to do these kinds of studies. So we don't have that kind of data.

The reassuring element of all this is that when we use these three different approaches or consider it two different, but that is expert elicitation plus outbreak data, and we have two expert elicitations and we're going to look at two outbreak databases, they produce very similar estimates. So you can say that the expert elicitation should be accounting for sporadic illnesses. That's using their expert judgment as to what percentage of all illnesses, outbreaks and sporadic, is caused by this food pathogen product type.

Now you could say, well, their perception is biased because they're more aware of outbreaks than sporadic illnesses. That's just a weakness in the data.

So my answer is I think this is the best we can do. We've used the best available data to come up with estimates. All four of the databases seem to indicate very similar attribution estimates.

MR. TYNAN: Ms. Jones, did you have a question?

MS. JONES: Yes, I do. Thank you. Cheryl Jones, Morehouse School of Medicine. In looking at all of the presentations for the morning, it's very clear that with the new reporting system, well, there's going to be an increase in the capability of reporting which in I guess in my eye, it also could be an increase in the number of public health concerns because the data could actually be considered more accurate. Or, on the other hand, it could be just the opposite, that there are not as many public health concerns as we may expect but I'm going to go with the first one, that there will be an increase in public health concerns.

What is in place to ensure that because of -- questions about data entry, accuracy of data, because it's new, what kind of quality checks are in

place to make sure that the data that's going into this new system is in place? And then secondly, what proactive type measures or considerations are going to be taking place to indicate that there are increased public health concerns with particular establishments?

MR. TYNAN: Okay. I'm going to let, Mr. Smith, I think you could address at least the first question.

MR. SMITH: Well, as I said earlier, we are going to use recognized ANSI standards on this. We report in OMB business cases on a quarterly basis and yearly basis on how we're progressing on these systems. We are going to have performance and user testing for every step of the way. As far as data entry, we will try and program in edit checks and then have to rely on our management control system which we're also automating, supervisors are overseeing inspection entry of data. When you get to more yes or no and less objective answers, then your data quality will also go up and you'll have, you know, edit checks for that but that's pretty -- we're

going to build it again using the ANSI standards and do performance and functional testing as we go along.

MR. TYNAN: Does that respond to your question, Ms. Jones? If you'd like to think about it, we'll come back to you again. Dr. Murinda, you had a question, and is this clarifying for attribution or we opening it up into --

DR. MURINDA: This is with regard to attribution.

MR. TYNAN: Okay. Thank you.

DR. MURINDA: In particular, with regard to the sources of data, the data that was collected by CSPI, 1990 to 2005 outbreaks, in one of the comparison tables that was showing the three studies, it does appear like CSPI does not have any data for *Listeria monocytogenes* covering beef, pork and poultry. Is there an explanation that they don't have data?

DR. TRAVIS: They had data. It didn't show any outbreaks, any illnesses associated with those food categories. I mean they're listing all of the outbreaks and then they list the food categories.

They didn't have outbreak data for those food categories.

DR. MURINDA: I guess it does appear like the sources of data we abstract for use in our outbreak data and other tools, we have to be selective --

DR. TRAVIS: One of the difficulties with both the *Listeria* and *E. coli,* of course, in looking at the outbreak data or any data is that they don't occur very often. So you have a pretty small database. The number of cases each year is fairly small. So almost -- well, at least with the CSPI data, they were all classified as deli meats. When I looked at the CDC data, they had a small number I think that were poultry but it was a small number, less than one percent. So it's not a big difference.

MR. TYNAN: Okay. Ms. Conti, do you have a comment?

MS. CONTI: I just have a question about the *Listeria* rate and how can you explain the drop? Is that based on incidence, to the .24, the estimates?

DR. TRAVIS: Oh, in the attribution.

MS. CONTI: Right.

MR. TYNAN: Yes.

MS. CONTI: Is that due to incidence or how did you determine that?

DR. TRAVIS: Let me find that. That's the 2010 public health objective. That's where they want to be is .24.

MS. CONTI: Okay. I thought somewhere when I was reading through the appendix that it said that that was met, that objective was met.

DR. CATLIN: Based on our testing, we are very close to meeting that. I can't remember if we're there or not, and I would let other people at the Agency speak to some of the activities that are going on these past two years, to be able to decrease *Lm* events?

MR. TYNAN: And that's -- I should say for purposes of the transcript, that's Dr. Michelle Catlin.

MR. TYNAN: Do you have further that you want to respond?

MR. SMITH: Well, again, we've had rulemaking that went into effect in 2003 and the Agency has put a lot of energy into following up with that rulemaking for *Listeria monocytogenes* and that, and we've focused our verification testing and follow up, of course, if it is positive. So all of that in combination is how we got an event.

MR. TYNAN: Okay. Mrs. Foreman, did you have a question?

MS. TUCKER-FOREMAN: Yes. Can you hear me okay?

MR. TYNAN: Yes, I think so.

MS. TUCKER-FOREMAN: Okay. I think the biggest question that comes out of all of these is that Dr. Travis acknowledges the data are limited. There are no sporadic data included. The Agency has decided to disregard the data that come from the nation's number one public health agency, the Centers for Disease Control. They looked on the website, but there's been no communication within individual researchers down at CDC. I think again that *Campylobacter* was the single biggest cause of

bacterial gastroenteritis. We have enough high quality data to go forward particularly with a poultry slaughter program or do you run the risk that -- on what is admittedly sparse data, will end up with other -- negative consequences.

And let me tell you one of the reasons why the results from these various studies may look so similar. If you go back and look at the people who participated in both the 2005 and 2007 FSIS elicitations and the Resources for the Future expert elicitations, you find that there is an overlap in eight -- Furthermore -- people, RFF and FSIS expert elicitations are listed as peer reviewers for FSIS' risk assessment. There may be a lot of reasons why you have some similarities here, and I don't think that all of them pass a scientifically appropriate standard.

MR. TYNAN: Okay. Dr. Travis, if you could respond.

DR. TRAVIS: Well, first I'd say that, yes, we acknowledge that the data on sporadic illnesses isn't all that complete. I explained some of the

problems with getting that data. I don't think that data set will ever be complete.

Second, we're not ignoring the CDC data. We acknowledge that it is an outstanding source of information. So we're now going back and estimating attribution choosing the CDC data, and as I said, our preliminary analysis indicates that it compares favorably with the Center for Science in the Public Interest.

Third, the Resources for the Future expert elicitation had 35 experts. Therefore, it was a much broader group. There was some overlap with the FSIS. We're only using one of the FSIS expert elicitations which is the 2007. I don't know what the number of experts that overlapped on that was but -- so you can have various reasons why the FSIS and the Resources for the Future expert elicitation agreed. I mean one would be that they had a few experts in common, but they also have a lot of experts that weren't in common.

The other would be they're all working from the same information. For instance, they all looked

at the Center for Science in the Public Interest database and said, oh, there's the attribution estimates though they aren't actually published. Their database just gives illnesses. You'd have to go through a lot of work to compute the attributions.

But I mean the reassuring fact to me is that the expert elicitations agree with the outbreak data. Both the Center for Science in the Public Interest and the CDC outbreak data, they're fairly similar. So we have two different approaches arriving at similar answers.

MS. TUCKER-FOREMAN: But you are comparing apples and oranges. To compare these data which are about illnesses to outbreaks is I think not appropriate, number one, and number two, the CSPI data, FSIS' outbreaks, were based on outbreaks. They acknowledged that they -- outbreaks. So they show a great deal of foodborne illness related to such diseases as vibrio vulnificus because -- in groups -- - number of people got sick according to the CDC -- cases. There are far, far, more people that get sick from *Campylobacter* than vibrio

vulnificus because -- much -- in groups. What number of people got sick according to the CDC sporadic cases? There are far, far, far more people who get sick from *Campylobacter* than vibrio vulnificus but it's only if you restrict yourself to the outbreak data that you come up with this strange list of problem -- does not relate what makes you sick. It's not real. It doesn't make any difference about what happens in the lives of the members of my organization day in and day out. It's not telling people and the USDA won't be helping people avoid getting sick from Camphylobactiosis. And you told us that -- because it's there. What I'm saying is I do not believe that there are sufficient data to make a commitment of enormous resources and -- given the limited -- this data, it's important for FSIS to refer this whole issue to the National Committee on Microbiological Criteria for Food. There should be a policy committee. They're the committee that looks at the science, and they need to look at these and say that these are okay to move forward on.

MR. TYNAN: Thank you, Mrs. Foreman. That

can be part of the recommendations of the Subcommittee and the Committee as a whole. So we certainly welcome that kind of a recommendation.

I have a couple of more questions here. Let me go to Mr. Kowalcyk. I'll go to him and then to Ms. Jones.

MR. KOWALCYK: Thank you. A couple questions about reconciling the expert elicitations again. What time period were the experts in the FSIS were they asked to provide their estimates on and was the questionnaire -- well, and also if you're aware of the timeframe of the resources for future studies and if they're consistent. And also, are the questionnaires consistent because in the technical report, there's actually an averaging across all three studies, and I'm just struggling with understanding whether or not that's the common practice in this type of analysis or if it's supported by precedence and it can be researched?

DR. TRAVIS: The expert elicitations, as far as I'm aware, didn't have a time period. They just asked them what's your opinion as to the percent

of disease that's coming from this food product for *Salmonella*? So presumably that means now, the present, when they were doing the studies. Since both studies were published in the same year, they're both sort of looking at approximately the same time period. I don't think they were actually done let's say within six months of each other. I don't know, but they were both published in the same year. So they're fairly contemporary estimates.

The outbreak database, we're looking over 14 years worth of data and getting an average. Now another approach would be don't use so much of that data because you could say that the old data isn't what's happening now. That's another approach. We could use that approach, and so only look at the last five years of data. I wanted to do that with the CDC data. I was going to look at how the estimates of attribution might change if we broke it up into different time periods or how they're evolving through time. We could ask those questions. We haven't asked them yet but our initial analysis was to use 14 years worth of outbreak data. The reason

the smaller number of years you use, the more variation and uncertainty you're going to get in the numbers because some of these outbreaks, you look at the outbreak data, you see like they have an illness. They have three illnesses. They have five illnesses. They have eight illnesses. And, then it says 780 illnesses. Those big illnesses can affect these numbers quite a bit if you don't consider multiple years.

MR. KOWALCYK: And my second part about averaging across the studies, is there a precedent in the research that recommends doing that?

DR. TRAVIS: Well, I'm not aware of any other study that's done what we did. I think this is the first time this has been done. People have been struggling with the attribution issue for years. There's been various public meetings on it. There have been groups estimating attribution but I don't think anybody has taken this approach of trying to look across these various databases to come up with estimates, and to compare what they're estimating.

And, oh, yes, we have subjected this

approach to peer review.

MR. KOWALCYK: When will the result of that peer review be complete?

DR. MACZKA: Actually it has been completed at this point, and we're in the process of examining the comments -- let me correct myself. I'm wrong. We had an initial period of just the attribution section but now we're subjecting this whole report to peer review. So we expect to even get even more comments. So the initial peer review of the attribution was about four experts. Now we expect to get input from like about seven experts. So we'll combine all of that and then advise accordingly.

MR. TYNAN: Is that it, Michael?

MR. KOWALCYK: Yeah, I'm assuming that the result of that study will be put in the Federal Register.

DR. MACZKA: Yes, we will prepare a comment and response document. Every comment we get, we will say what the comment is and then what our response is, and it causes us to revise the report accordingly. So that will be publicly available.

MR. TYNAN: Ms. Jones, you had a question and then I'll come back to you, Mrs. Foreman, I think you had a question as well.

MS. TUCKER-FOREMAN: I do. Thank you.

MS. JONES: Okay. Thank you. I think a part of my question got lost, or my original question. What I was asking about, I'm king of looking for future plans or kind of forward moving because they were looking at data that is given, not what's happening now but what about the future? Because when you're looking at the new system, you're actually having present establishments to be more accurate in their filing quality control. So, if you find something that you did not expect to find, will this system be able to move forward? Will you be able to make whatever modifications? Will you be able to make whatever changes? How will that kind of information be presented to the public in a manner that they can understand and be able to act in a positive way even if it looks like there are greater public health concerns than there may necessarily be? What -- are in place?

DR. CATLIN: This is Dr. Michelle Catlin. The way that the system is currently being designed with the whole PHIS, Public Health Information System, is to design it to be as flexible as possible so that as science evolves or knowledge evolves, it can evolve with it. One of the aspects of it is it will have the ability through predictive analytics to be able to go in and flag and provide alerts if things aren't being done in an establishment or are being done too often in an establishment. So they'll have those flags designed in there so that we can then on the human side look at the flags and go back and correct and make sure things are being done correctly by establishments, do those corrections that way. And then as information evolves, we will be able to evolve the system as we go along.

MR. TYNAN: Does that respond to your question, Ms. Jones? It sounded as though you had another aspect of that?

MS. JONES: No, that's fine.

MR. TYNAN: Okay. Thank you. Other questions? Ms. Foreman, did you have a comment or

question?

MS. TUCKER-FOREMAN: Yes. Again, I'm surprised that the Agency is bringing to the Committee without having a peer review. Dr. Travis acknowledges that it is unique. No one has used the numbers this way before including trying to average outbreaks and expert elicitation and I just looked again at three peer reviewers for the FSIS versus -- served on an FSIS expert elicitation panel. All of them served or two of them of the three served on the RFF group -- reviewers are from the same department or the same university. If you're going to do a peer review, it really has to be I think a little more broad based than that. None of the peer reviewers are human health experts. They are not medical doctors, and I urge you to have some medical doctors involved. According to RFF, 25 percent of the expert elicitation panel really should be medical doctors, and that was never true in either of the -- elicitations. So there is I think an unacceptable bias in all of the documents that constantly overlap.

Again, I will tell the Committee as a

whole, I think the place to get this looked at is in the National Advisory Committee on Microbiological Criteria for Food.

MR. TYNAN: And we are certainly welcoming that kind of a recommendation. I just had sort of a sidebar conversation with Dr. Maczka and I think if there are other peer reviewers that the Committee would recommend to us, I think we would be willing to entertain that and expand our peer review group. So we're welcoming those kinds of comments as well.

Are there other burning questions from the Committee at this particular point? A lot of information this morning.

(No response.)

MR. TYNAN: Okay. So it's about 12:15, and I think we're right on time with our agenda, which is good. We have a lunch break of an hour. Before everybody leaves, there are listings outside of the local restaurants around. Many of them are on a place called Wilson Boulevard, and as I understand it, you have to go out the front of the hotel and take a right and look around. It's back up toward

the Metro. So for anybody who came Metro, that's where Wilson Boulevard is. It's up a couple of blocks. We've only allowed for an hour. So we're hoping that you'll come and go quickly.

We have this afternoon, two Subcommittees. One of the Subcommittees will be chaired by Mr. Elfering and just for purposes, Mr. Elfering's group will be in this room and, Mrs. Foreman, you'll be participating by phone with Mr. Elfering, but the Committee is Cheryl Jones, Mark Schad, Dr. Rybolt, Mr. Stromberg, Dr. Negron, Dr. Cutter if she's available, and again Mrs. Foreman. So that's Kevin Elfering's Committee. You'll be meeting here.

The other committee for issue number two will be led by Dr. Dickson and Dr. Dickson's Committee is Craig Henry, Ms. Conti, Ms. Grondahl, Dr. Murinda, Mr. Covington, Dr. Harris and last but not least, Mr. Kowalcyk. So that group will be meeting on the other side of this partition. It will be on this hallway but there should be a meeting room over there.

We'll have a computer and a printer in each

room. We'll also have a person to help transcribe the reports, and the FSIS people will distribute themselves to help with the comments, the questions, the issues that come up and so that there's a substantive dialogue.

I would suggest to you as quickly as you can get back from lunch, please do so. We've only allowed for about 2 hours and 45 minutes for the Subcommittee conversations and reports.

DR. CUTTER: Mr. Tynan, this is Catherine Cutter from Penn State. Do we just dial back in at this number to participate in the Subcommittee group then?

MR. TYNAN: Absolutely, Dr. Cutter. Nice you could join. And we'll have the questions for the Subcommittee when they come back.

DR. CUTTER: Okay.

MR. TYNAN: And, Dr. Cutter, I e-mailed them over the weekend. So you should have them available to you on your computer.

(Whereupon, at 12:15 p.m., a lunch break was taken.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(4:00 p.m.)

MR. TYNAN: Let's get started. Good afternoon.

We've had some lively discussions with our Subcommittees on the two issues that we presented today, and as I mentioned earlier, unlike previous meetings, we're doing report outs individually. So we had a Subcommittee discussion and now we're going to do the report outs for those discussions. I would say probably both Chairpersons will probably want to take a little time tonight or maybe in the morning to kind of clean up their reports if that's necessary and we'll make those the final. But we will sort of come to conclusion on them tonight.

So with that, I'm going to introduce again Mr. Kevin Elfering, and Mr. Elfering was working on the public health attribution and volume question. So, with that, Kevin, if I could impose on you to -- ah-hah.

MR. ELFERING: Dr. Raymond was hoping you were going to say I should clean up my act.

(Laughter.)

MR. ELFERING: Well, actually, first of all, I'd like to thank our Subcommittee, Cheryl Jones, Mark Schad, Michael Rybolt, Stan Stromberg and Edna Bravo, and also Catherine Cutter and Carol Tucker-Foreman, who were with us by telephone. I'd also like to thank Ellyn Blumberg with FSIS and also the FSIS technical people that were able to help us go through some of this information, and also the industry people that participated and the consumer groups and really everyone who participated. Everyone had some valuable information and I think we have come up with a good report, although I'm sure that it will have some modification eventually.

I was told though by Dr. Dickson that they had a lot more questions and they finished earlier than we did. So I don't know if that has any correlation with anything at all.

The issue is public health attribution and volume, and the first question is what recommendations does the Committee have regarding enhancing methodology and data sources used by FSIS to calculate

and use public health attribution?

To be sure FSIS actions contribute to reducing foodborne illness, the Committee recommends that before moving ahead on the new inspection system, FSIS acquire more robust data on the relationship between specific foods and illnesses attributed to a particular pathogens. FSIS should have sufficient data on *Campylobacter* to establish a performance standard. The Agency should consult with CDC on the best way to factor into the database the impact of sporadic illnesses. *Salmonella* serotype information should be factored in as well as should sporadic cases of other pathogens.

The Committee believes that FSIS should not refer to the programs in development as risk-based or public health-based until it has more robust data including a true national prevalence number as well as enumeration and serotype information. The Agency should ask the National Advisory Committee for the Microbiological Criteria for Food, for assistance in establishing appropriate data to be used and ways to avoid methodological problems in using limited data to

develop the inspection levels.

The Subcommittee strongly recommends the inclusion of serotype data in the data analysis and how it relates to public health.

The Committee encourages FSIS to evaluate the utility of more contemporary microbiological technologies in Agency testing and for foodborne attribution. FSIS should use the most current and validated methodologies and work with USDA, ARS, other public health agencies, universities, schools of public health, and others, to look at these new methodologies.

The Committee would be interested in hearing updates of the Agency's progress on new methodologies and especially on this meeting that is scheduled for March with ARS.

So before we go onto the second one, are there any comments or questions?

MR. TYNAN: And we'll use the same procedure that we did earlier, stand your tent card up and then we'll go around and call on you that way.

(No response.)

MR. TYNAN: No questions. Mrs. Foreman, Dr. Cutter, if you're on the line.

MS. TUCKER-FOREMAN: I don't have any proposed changes.

MR. TYNAN: Okay. Kevin, if you want to go to question 2.

MR. ELFERING: I'll go onto issue 2. What recommendations does the Committee have regarding how to better use volume for ranking establishments within the second level of the Public Health Risk-Based Inspection System?

FSIS should differentiate product destined for fully cooked product separate from raw product volume, and FSIS should use pounds of product shipped, not pounds of product produced. The consumer is not exposed to pounds of product produced especially if some of the product is being held. FSIS needs to consider the fluctuation of production volume due to seasonality.

Many of these were discussed at the last Advisory meeting where we had to work on volume as well, and it would probably be a good recommendation

for the Agency to review those issues that we talked about at the last meeting.

MR. TYNAN: Did you want to include that Kevin?

MR. ELFERING: Maybe we should put something in there that in the last National Advisory meeting, a Subcommittee did discuss issues with volume and the Agency should refer to those recommendations as well.

That's it. That takes care of it.

MR. TYNAN: Comments or thoughts from the Committee or from FSIS to clarify?

(No response.)

MR. TYNAN: Kevin, I think you've established the all time record for reporting and being done, or at least during my tenure of the Committee.

Okay. Kevin, thank you very much, and I thank the Subcommittee for doing that work.

What we need to do at this point is generally, does the full Committee consider these to be the recommendations that they want to put forward to the Agency? Let's do it this way? Are there any

dissenters?

(No response.)

MR. TYNAN: There being none, I will assume that this is the recommendations of the Committee.

And, Kevin, if you could clean up your act and also the report, that would be great.

And I'm going to turn it over at this point if there's no other questions or comments on this piece, I'm going to turn it over to Dr. Dickson to talk about the across establishment public health risk-based establishment algorithm. And you had the challenging four questions. We gave Kevin the easy task today.

DR. DICKSON: Right. Our Subcommittee Number 2 did have questions which of which revolved around NRs, noncompliance reports and again I would like to thank the Subcommittee, Craig Henry, Kibbe Conti, Andrea Grondahl, Shelton Murinda, Brian Covington, Joe Harris and Michael Kowalcyk, as well as those who were in attendance in the audience. We had very good audience participation, and I believe it was very useful to the overall discussion of the issues,

and I wanted to thank them.

The questions that we had, forgive me, I'm a little disjointed here, here we go, as I said, most of these related to the issues of noncompliance reports and where this fits in is in the conceptual approach to the public health risk ranking, where we have a magnitude component and a hazard or indicators of process control component, and these mostly come into part of the measure of the hazard or the indicators of process control.

The first question was what data analysis, in addition to those that have been done by FSIS, would the Committee view as helpful to the Agency in assessing the utility of the inclusion of inspection observations, including those recorded as NRs, in its public health risk-based inspection algorithm?

And one of the first things that our Committee noted was that there's a considerable amount of variation in NRs related to say geography of the establishment, seasonal variation, perhaps establishment-to-establishment variation, and in some cases, perhaps inspector-to-inspector variations.

This is to be expected when you're dealing with people. There will be variations.

Our interest in the Carnegie Mellon analysis was we need to look at it more detailed. We need to see how this was looked at, which NRs, looking at the health-related NRs that FSIS selected, the industry NRs, all the NRs. We were curious, for example, what percentage of the overall NRs do the health related or the FSIS NRs actually represent? I mean are we looking at 1 percent of the total NRs that are written? Are we looking at 10 percent, 50 percent, things like that.

Some real concerns with that. We're wondering about those NRs as they are spread out over different production processes, whether it is really fair to use a NR or a raw product or a broiler, for example, with a fully cooked ready-to-eat product if that's part of the same analysis. We wanted to look at the Carnegie Mellon analysis in more detail. Also concerns about a cross species, whether it was reasonable to look at NRs in a poultry slaughter facility versus a pork slaughter facility.

The second question related to a 30-day time window, and the question was, for the purpose of illustration, a 30-day time window was used for calculating NR rates in the proposed algorithm. What time window would the committee propose for calculating NR rates and or what criteria should be considered in establishing a time window?

I think it was the consensus of the Committee that we really can't say whether the 30-day time window is a good time window or a bad time window or an okay time window. We really don't have the information to make that decision. We had a discussion about whether we should be looking at time frame versus production volume. I believe it was the consensus of the committee that we should probably be looking at a timeframe, whether it's a 14 day or 28 day or whatever time period, that we should, in fact, be looking at a timeframe.

There was a comment made by one of the Subcommittee members that we should, in fact, just start somewhere and that in the absence of anything else, 30 days is probably as good as anything. We

should use that as a starting point, run the algorithm and then evaluate the results. And in a sense, this could be done as sort of a sensitivity analysis, look at a 7 day, 14 day and a 30 day, or even 60 day, run the algorithm, look at the results that come out and the FSIS staff that were present indicated that this is being done right now but we simply don't have the results in front of us.

The third question was what other recommendations does the Committee have regarding how NRs can be used to establish levels of inspection? And I think the point is, that that component of the algorithm is really trying to capture the day-to-day events in the establishment as opposed to some type of event or episodic event, recall or positive test for O157:H7. And we felt it was important that we do, in fact, capture the day-to-day events.

Now NRs may or may not be the best way to do that, and we may have some questions about how we're putting all that in the algorithm but I think I'm speaking for the Subcommittee here when we say that we thought that it was important to capture those day-to-

day events in consideration of the risk ranking of a particular establishment.

And again we deferred on that question as well saying we'd like to see the results of the preliminary runs of the algorithm to see what the results look like.

The fourth question was what other recommendations does the Committee have regarding the use of process control indicators included in the algorithm and process control indicators, and I'll read this directly from the slide include -- by the way, this is slide 5 in Dr. Travis first presentation, across establishment ranking concept for processing and slaughter. Indicator of process control, under that definition, include measures over time, verification testing, health based NRs, episodic measures, FSAs, recalls, enforcements. The FSIS staff also indicated that those indicators of process control would include the same criteria used in establishing levels of inspection. So that would include things such as positive tests for *E. coli* O157:H7, being associated with an illness or an

outbreak, things of that nature. We felt that the list that FSIS had compiled was fairly comprehensive. Given the timeframe we were working under, we really didn't have any additional suggestions to incorporate as far as other indicators of process control.

And with that, and I would emphasize that this is a draft version of the report as the Subcommittee has not had a chance to review it. So I'd like to give them an opportunity to offer any additional comments at this point in time.

MR. TYNAN: That's fine. We'll take a few moments in the morning to revisit the report to make sure everything was okay.

With that, if Dr. Dickson doesn't have anymore to report, then I'll open it up for questions from the Committee.

(No response.)

MR. TYNAN: Mrs. Foreman, I think we e-mailed the two reports. Did you have any comments on this one?

MS. TUCKER-FOREMAN: No, I don't. Thank you.

MR. TYNAN: Okay. Kevin, I think Dr. Dickson may have broken your record.

Okay. Then we'll revisit this in the morning, but generally do we have consensus that some of the things that Dr. Dickson talked about are worthy recommendations?

(No response.)

MR. TYNAN: Okay. We'll revisit it again in the morning.

MS. TUCKER-FOREMAN: Can you give a message to Kevin please, that I found a couple of typos in this, and I'm going to send it back and then he can resend it to me with those marked.

MR. TYNAN: Yes, we'll resend the material to you to make sure you have it.

MS. TUCKER-FOREMAN: I found a couple of typos. I'm going to send it back to you all, if you'll give it to Kevin.

MR. TYNAN: Okay. I misunderstood. I'm sorry. Fortunately, Ellyn can hear better than I can I guess.

Okay. With that, if there are no other

comments on the reports from the subcommittees, then we're to the point in the agenda where we have public comment. I would, before we introduce any of the members of the public that would like to make a comment, I wanted to mention to you that in our Federal Register notice, I think we had suggested comments going to the NACMPI e-mail box, and we have established a special mailbox for this program, so that after the fact, I think it'll be a little bit easier for you to identify and find it than coming to the NACMPI mailbox. So we have a new mailbox, and we'll get this out on the table in the morning, but it is going to be called publichealthbasedinspection, one word, @fsis.usda.gov. So we'll have a continuing dialogue with you and you can send comments to that, and we'll make sure that the appropriate people have access to that mailbox. We'll get your comments and factor it in as this process evolves. So we do have a new mailbox, and as I say, I'll have something for you in the morning. We'll have it out on the table so you can take that away with you if you have comments after the meeting.

And with that, I'm going to -- I think we had one person that signed up for today, and then I'll open it up for anybody else that would like to comment. I believe Felicia Nestor, you signed up for a comment.

MS. NESTOR: Felicia Nestor, Food and Water Watch, and I think probably none of you here are not surprised at one of the comments I'm going to make. But the first thing I wanted to support -- what Dr. Negron said that just because something is, this is my interpretation of what she said, just because something is in the HACCP rule doesn't mean that it's being implemented in the field. So as a consumer, I'm not confident just because something is written on paper. I need to know that it is actually being implemented.

I was sitting in the room on the use of NRs and I thought, if I heard it correctly, several people that I would say are more from the industry side were recommending that the Agency test drive the algorithm and I would really like to support that idea. The idea of rolling this thing out by implementing it in

every plant around the country just doesn't make sense to me especially since there are so many unknowns with it.

On Appendix B of both technical plans, the prompts, I have some questions about how well and easily that's going to be implemented. It seems to me that several of these questions are going to be difficult to answer as yes or no. For instance, if you, if the inspector has to answer the questions, is the establishment implementing prerequisite programs -- processing as per their hazard analysis, I mean that requires first of all the inspector determine whether that was the cause of the non-compliance and what do you do if there are several aspects of the prerequisite programs. How do you answer yes or no when there are five different aspects. So I really think that that's one of the main reasons I think this algorithm and this prompt system should be test driven, and you're going to have to work the kinks out.

And now the comment that I always make and I'm sure it will surprise no one. When I was in

elementary school, or high school, I can't remember the last time I read about the scientific methods, but if you were doing an experiment, you record every single factor that could have an impact on your outcome, and the Agency has not recorded whether there are no NRs in a plant because the inspector hasn't had time to write the NRs or because the inspector has not had time to do the inspection test in that plant.

I think that if a particular plant has a -- absence of an inspector, some of the findings in that plant or some of the occurrences later could eventually be linked to the fact that you had half or a quarter or, you know, 10 percent of the normal -- inspections that that plant is supposed to have. And I think that to the extent that this proposal is going to be heavily driven by NRs, it's indispensable that you have inspectors record when they do not do an inspection test because they didn't have the time. I mean that's just from your program. As a consumer and as a taxpayer, I just don't know how you can even have the chutzpah to say that your system is transparent if you're not going to allow us to determine whether the

staff -- So -- and I mean I know OIG recommended this many years ago. I keep talking about it. I really think you need to do this. Thank you.

MR. TYNAN: Thank you, Ms. Nestor. Felicia was the only person that signed up, but I will allow others to come to the microphone if you could introduce yourself and your affiliation.

MS. BUCK: My name is Pat Buck, and --

MS. TUCKER-FOREMAN: Robert, this is Carol. I'm having trouble hearing. Could you maybe get closer to the mic.

MR. TYNAN: Okay. We'll do it. Thank you, Carol.

MS. BUCK: My name is Pat Buck, and I'm with the Center for Foodborne Illness Research and Prevention, and first of all, I just have a comment to make to the NACMPI Committee. I applaud all of you because you, like Dr. Raymond, like all the consumer groups, was given a bulk of information almost 10 days ago, 11 days ago, and I have already voiced that as inappropriate to have FSIS dump us with that much reading material in such a short period of time to

digest. I just wanted to make that clear. I think FSIS has a responsibility to those of us who are spending huge amounts of time to help you come up with a plan that is workable, that we have time to really review that information so that we can respond in a thoughtful fashion. All right. So it's a criticism not of the people on the Committee, of course, but I think FSIS in the future should not do that one again, in particular to Dr. Raymond, who has a lot of responsibilities, too.

As far as the plan, well, I'm all in favor of doing things to improve food safety. I think everybody in the room knows that. I would like to see some indication that we're not going to go down the road that was traveled once before when we put together a HACCP rule and then we didn't have the means with which to implement it, to really bring power to our new methods for controlling foodborne disease in this country.

I think what a lot of people need right now from the Agency is some indication that your intent is to make this a sustainable system, so that when all of

the things that Felicia talked about with the NR reporting, so that when new innovations are brought to a industry, when they put new technology in place, it's going to really reduce their risk for foodborne pathogenic loads, we need to have a mandatory trace back system, and I would like to see the Agency go after that, with as much vigor as they would do building this system here.

Your system is only going to be as good as the data and I know I've talked frequently about the need to get more data and I'm very proud of the Agency for the efforts they are making to, you know, collect more data, but until we have a lot more points and you would get a lot more points if you had a trace back system, I don't see how you are going to really build this transitional system that you are now proposing into a sustainable system that's going to protect the large population of Americans that are already here but there's more coming on the horizon. And so I think the challenges that we have are to build a strong system and I hope that the input that not only consumer groups, but the industry and NACMPI have

given you will give you some guidance into the direction you need to go, but you're going to have to have mandatory trace back, and that includes mandatory animal ID and you're going to need realistic and enforceable performance standards. Thank you.

MR. TYNAN: Thank you, Ms. Buck. Do we have any other comments from the public at this time?

(No response.)

MR. TYNAN: Okay. Dr. Raymond, did you have a comment you wanted to make?

DR. RAYMOND: Yeah, I'd like to respond to both Felicia and Pat, and thank them for their comments and for coming and contributing also. I know Pat's down for the Food Safety Education Partnership, a two day meeting. So she's kind of combining two meetings. So when she talks about us having lots of things to do, we know Pat's got lots of things to do, too and, of course, we'll defend Pat and I had this conversation, I mentioned it earlier this morning. We'll defend the 700 page data dump because most of it was appendices and appendices, a lot of people get into the weeds as much as they want or just the 30

page summary if that's all they want, too. So we will continue to do things like that. We used to be criticized when I first got here for not supplying anything just prior to a meeting. I think there's one meeting Mike might have got something to read on the airplane just before he left town and that was the first meeting I had came to. I promised Mike we would never do that to him again. So this time you had to carry an extra suitcase, of course, to bring the stuff but we are doing it in an effort to get better.

Pat, I'm with you all the way on sustainability. You know, you come to this town, this Government for three years, you're going to see a whole lot of changes, but by golly, anything you do change, we want to make sure it continues for a long time. Otherwise, it doesn't work, the three years, to try to create the change. So we're doing everything we can to build sustainability into this, including this PHIS, which I know everybody had made the comments, well, when's it going to deliver. Show us. I'm a little bit of a nay sayer, too, when it comes to IT but we're putting a lot on that and on Bill Smith

and his crew and our contractors and our other IT folks and it is a make it or break deal I believe for this new system. And that will be sustainable, of course, once we build that baby. It will be good for at least several years, and as you know with IT, you've got to keep moving it and we'll have a baseline there that we only dreamed about a couple of years ago,

Track back, I'm with you, Pat, most of the way. Mandatory animal ID, I'm not, but we are doing better with trace back than we were a few years ago. We could still do better. We need to find ways to get better. Of the recalls for *E. coli* this summer, a couple of them were related to trace backs and recalls from slaughter facilities because of a recall that involved a grinder, and we are making a serious effort to find, you know, the origin of the problem, to go upstream so to speak, some of the things that Carol Maczka talked about in the plant. Instead of just doing the NR, going upstream and try to find what caused the NRs, you know, it's just a baseline.

And then, Felicia, for you, God bless you

for bringing it up every time you get up and talk because Topps really was an eye opener to me, and this new PHIS system is going to help prevent things like that. If there is an outlying plant or inspector or circuit that is writing fewer NRs than anybody else in that district, they're going to be looked at with a FSA. On the contrary, if there's a plant or an inspector or circuit that's writing way more NRs than anybody else in that district, we're going to look at that one, too, because some of the variability from individual to individual, which we've talked about for two and a half years, how we're going to use NRs, it's still there but we're trying to find ways to decrease that variability with increased supervision, increased training and increased education, but also using PHIS so that analysts, who don't have time to go through, I think as Carol mentioned, how many plants, how many inspections days, you know, et cetera, that's an awful lot of stuff to go through for a human, an analyst in each district. And I do believe with PHIS, it's one of those things, that's why we're bringing NRs into this equation because we do believe we will be able to

decrease some of that variability.

Now if we cannot, I'm terribly opposed to the 30 day, Dr. Dickson. I believe if we have that much inspector variability, which Felicia reminds us of, and part of it's the inspector, part of it is the time they have to do their job, there's no question about that. And part of it is their supervision, and we've got to decrease that variability if we're going to use a 30-day timeframe.

So, Felicia, another one of your regular criticisms and well received one is we don't know why an inspector, if they did or didn't do a procedure, why they didn't do a procedure, that's a management tool that we're committed to, and we listen to you. And like I said, Topps opened up some eyes and we're working on that also to put that into our management system. So you're going to have to find something else to talk about I hope. I hope.

MS. NESTOR: I will as soon as I see the change.

DR. RAYMOND: I know. I understand. I understand that also, and we're going to try to get

there as soon as we can. Thank you.

MR. TYNAN: I spoke with Mr. Almanza while Dr. Raymond was speaking, and I think he felt that Dr. Raymond was covering it. So he's graciously relinquished his final comments for the day in the interest of you've had a long day, a lot of discussion. So while we have the opportunity to close, I think we're going to do that.

We will start again at 8:15 in the morning. We will be in this room. If you want to take your books, I know everybody will be studying tonight over dinner and looking at the material for tomorrow. However, if you've already got it committed to memory and want to leave it here, you're welcome to do that as well. So you can do that.

So I'll see you at 8:15 in the morning. Thank you.

(Whereupon, at 4:45 p.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

PLENARY SESSION

Arlington, Virginia

February 5, 2008

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

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SEAN WILLIAMS, Reporter

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